UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NICHOLAS SKIADAS, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ACER THERAPEUTICS INC., CHRIS SCHELLING, and HARRY PALMIN, Defendants.	**CASE No.: 1:19-cv-06137-GHW** **THIRD AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** **CLASS ACTION**

Lead Plaintiff Nicholas Skiadas ("Plaintiff"), by Plaintiff's undersigned attorneys, individually and on behalf of all other persons similarly situated, alleges the following based upon personal knowledge as to Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys that included, among other things, review of documents produced by Defendants along with Defendants' public documents, conference calls, and public announcements, the United States Securities and Exchange Commission ("SEC") filings of Acer Therapeutics Inc. ("Acer" or "Company"), wire and press releases, and other information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action brought on behalf of a class consisting of all persons and entities, other than Defendants[1] and their affiliates, who purchased or otherwise

[1] The Defendants include: Acer; its president and chief executive officer ("CEO"), Chris Schelling ("Schelling"); and its chief financial officer ("CFO"), Harry Palmin ("Palmin").

acquired Acer's common stock from September 25, 2017 through June 24, 2019, both dates inclusive (the "Class Period"), and held the stock until the end of the class period. Plaintiff pursues remedies against Acer and certain of its officers and directors for violations of federal securities laws.

2. Acer is a development-stage pharmaceutical company that touts itself as focusing on "the acquisition, development, and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs."

3. This case concerns Acer's effort to commercialize celiprolol, a drug in the beta-blocker class, in the United States under the trademark "EDSIVO" for the treatment of a rare genetic disorder known as vascular Ehlers-Danlos Syndrome ("vEDS"). The Company devoted well over 80% of its research and development expenses to EDSIVO from 2013 through the end of 2018.

4. Celiprolol has not been approved for any indication in the United States, but has been approved for the treatment of hypertension in the European Union since 1984 and is available there as a low-cost generic drug. Celiprolol is not approved for use in vEDS patients in Europe, but is prescribed off-label[2] to vEDS patients there. Although celiprolol is not approved by the FDA, patients can be import it for personal use, including through online pharmacies. Other, similar beta-blockers, that are available as low cost generics, are used to treat vEDS patients in the United States.

5. Instead of sponsoring its own clinical trial to test the efficacy of celiprolol on vEDS patients, Acer purchased an old study from France, published in 2010, which consisted of only 53

[2] A drug is prescribed off-label when a doctor prescribes it for a condition that a government drug regulatory agency did not approve it for. A drug's manufacturer cannot market a drug for off-label use, but doctors are not limited to writing prescriptions for approved indications.

patients (the "Ong Trial"). The Ong Trial was the center piece of the failed New Drug Application ("NDA") that Acer submitted to the Food and Drug Administration ("FDA") for EDSIVO.

6. The FDA has a program to encourage research into treatments for rare diseases that grants seven years of marketing exclusivity for drugs intended to treat a rare condition, which are known as "orphan drugs." Acer had no intention of conducting any new clinical research or trials or generating any original data for the effectiveness of celiprolol for its EDSIVO NDA. Instead, Acer only confirmed the existing data by conducting a "retrospective source verified analysis" of the Ong Trial. Additionally, celiprolol is available as a cheap generic drug in Europe. Nevertheless, according to analysts, Acer intended to use the FDA rules meant to encourage funding research into drugs for rare diseases to gain market exclusivity that would allow Acer to charge vEDS patients more than $100,000 a year for EDSIVO.

7. Less than a year after acquiring the rights to the Ong Trial data, Acer became a public company through a reverse merger in September 2017 and needed to raise a significant amount of money to continue as a going concern.

8. In the prospectus and prospectus supplement for its December 2017 secondary offering, Acer claimed that "***the FDA agreed that additional clinical development is not needed***" for EDSIVO (emphasis added). Acer made similar statements about the FDA's view of the Ong Trial in its 2017 Form 10-K and its prospectus supplement for another secondary offering that it completed in August 2018. On the strength of its representations that the FDA would approve EDSIVO based on the Ong Trial Data, the Company raised gross proceeds of $12.56 million from its December 2017 offering and $46.0 million in gross proceeds from its August 2018 offering.

9. Acer, however, never had any such agreement with the FDA. Instead the official FDA minutes of Acer's September 30, 2015 meeting with the FDA show that when Defendants

asked the FDA if the Ong Trial "provides sufficient efficacy support for celiprolol in the treatment of vEDS, and ***that no additional clinical studies will be needed for NDA approval***?" the FDA responded: "The literature may support filing an NDA. We should note that approval based ***solely*** on the published report of a single study is ***rare***." (emphasis added.) This is definitive proof that Acer's statements to investors that "the FDA agreed that additional clinical development is not needed" and "the FDA agreed that an additional clinical trial is not likely needed" were false and misleading.

10. The official FDA minutes of Acer's June 28, 2018 meeting with the FDA show that Defendants again asked the FDA if it agreed that the Ong Trial supported the efficacy of celiprolol, and the FDA again stated that it did not agree.

11. Defendant Schelling, the founder and current CEO of Acer, attended all the meetings that Acer had with the FDA concerning EDSIOVO, including both the September 30, 2015 and June 28, 2018 meetings.

12. Additionally, starting with Acer's May 18, 2017 meeting with FDA, the FDA told Defendants in at least five meetings and other correspondence that the Ong Trial had serious flaws: (1) that it had a randomization imbalance between the celiprolol and control groups, and (2) the Ong Trial's results were not properly adjusted for the multiple interim analyses of efficacy conducted during the Trial and that the Trial was stopped early based on those improperly conducted interim analyses. When Acer did conduct the proper analyses requested by FDA, the Ong Trial failed to show efficacy. Based on those flaws, the FDA concluded that the Ong Trial was not sufficient to show that EDSIVO was effective against vEDS and its results were not statistically significant.

13. The Ong Trial's celiprolol and control groups were imbalanced in multiple ways

that biased the Trial. The researchers discovered during the Ong Trial that 20 of the 53 participants did not have the mutation that causes vEDS and there was a severe imbalance between the study's celiprolol and control groups regarding the mutation. While only 52% of the 25 patients in the celiprolol arm were confirmed to have vEDS, 71% of the 28 patients in the control group were confirmed as having the genetic mutation. The celiprolol and control groups were also imbalanced due to a higher percentage of people in the control group who had: a family history of vEDS; a personal and 1st degree relative with a history of arterial rupture or dissection and uterine or intestinal rupture; and a phenotypic presentation that indicated they were sicker, including a higher incidence of acrogeria, hypermobility of joints, tendon rupture, lower limb varicosity, and bruising. Because of the imbalance between the treatment and control groups, there was a clear-cut bias in the Ong Trial towards a finding of a treatment benefit for the group of patients taking celiprolol. This led the FDA to warn Acer beginning in 2017 and to conclude that the results of the Ong Trial were not statistically significant.

14. The FDA also warned Acer repeatedly that the Ong Trial did not adjust the p-value (or level of significance) necessary to achieve statistical significance to compensate for the multiple interim analyses that were conducted before the conclusion of the Trial. Conducting multiple interim analyses introduces additional error into the results of a clinical trial because repeatedly looking at the data increases the chance that an indication of efficacy could be the result of random chance. This was an especially serious problem because the Ong Trial was terminated early based on those improperly conducted interim analyses, which was compounded because the results were not statistically significant when the study was terminated nor at any of the preceding interim analyses. The Ong Trial was terminated after only enrolling 53 patients, even though researchers had intended to enroll 100 patients and many of the enrolled patients were not

monitored for the full 5-year duration that the original trial plan called for.

15. Defendants failed to disclose any of the FDA's warnings about the flaws in the Ong Trial, which the Agency communicated to Defendants repeatedly over a period of more than two years before it rejected EDSIVO's NDA for those same reasons. Instead, Defendants stated that the results of the Ong Trial were "statistically significant" and it was a "robust clinical study." Defendants also repeatedly misrepresented that important phenotype characteristics were "equally balanced between celiprolol and control" in the Ong Trial.

16. Near the end of the Class Period, on April 16, 2019, Defendants announced that French researchers had published additional data. The publication "describe[d] outcomes in 144 COL3A1-positive vEDS patients clinically monitored and treated at the French National Referral Center for Rare Vascular Diseases (Paris, France) between the years 2000 and 2017" (the "Long-Term Observational Study"). As with the Ong Trial, that study was deeply flawed. As explained by the researchers of the study, "[i]t is difficult to formally assess this beneficial effect (the benefit of celiprolol on survival)" because the study did not have a control group.

17. On June 24, 2019, the FDA issued a Complete Response Letter (the "CRL") denying Acer's NDA for EDSIVO because the Ong Trial "does not provide substantial evidence of effectiveness for celiprolol" in vEDS patients. The FDA found this for the same reasons it had been warning Defendants about for more than two years — that the study was prematurely terminated based on flawed interim analyses before efficacy was established and because there were "important baseline imbalances" in the Trial. The CRL further stated that "[t]o address these issues, it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS."

18. Before the market opened on June 25, 2019, Acer announced that the FDA had

issued a CRL denying EDSIVO' s NDA. Defendants admitted that the CRL highlighted the need for Acer "to conduct an adequate and well-controlled trial," necessarily finding that the Ong Trial did not meet that threshold. Accordingly, it was clear that the FDA never agreed that no additional clinical development for EDSIVO was needed. Given Acer's statements about what the FDA agreed to, its positive statements about the Ong Trial, and the fact that Defendants failed to disclose any of the FDA's criticisms of the Ong Trial, this news shocked investors and sent the price of Acer common stock plummeting by $15.16, or over 78%, to close at $4.12 on June 25, 2019.

19. As a result of Defendants' knowing and/or reckless false and misleading statements and omissions concerning the FDA's statements to Acer about EDSIVO, the value and price of Acer common stock during the Class Period was artificially inflated. When the FDA's issuance of the CRL revealed the truth and Acer's share price declined, Plaintiff and other Class members suffered significant losses and damages.

JURISDICTION AND VENUE

20. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

21. This Court has jurisdiction over the subject matter of this action pursuant to § 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. §1331.

22. Venue is proper in this District pursuant to §27 of the Exchange Act, 15 U.S.C. §78aa and 28 U.S.C. §1391(b). Acer securities trade on the Nasdaq Stock Market ("NASDAQ") located within this District. In addition, substantial acts in furtherance of the alleged fraud or the effect of the fraud have occurred in this District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this

District.

23. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

24. Plaintiff, as set forth in the Certification submitted in connection with Plaintiff's lead plaintiff motion filed in this action, (ECF No. 14-2), acquired Acer common stock at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

25. Defendant Acer is a Delaware corporation with its principal executive offices located at One Gateway Center, Suite 351, 300 Washington Street, Newton, Massachusetts. Acer's common stock trade in an efficient market on the NASDAQ under the symbol "ACER."

26. Defendant Schelling founded Acer in December 2013 and has served as Acer's president and CEO since February 2016. He served as the Company's chief operating officer ("COO") from December 2013 until February 2016.

27. Defendant Palmin has served as Acer's CFO since February 2016 and COO since September 1, 2018. Defendant Palmin served as president, CEO, and board director at Acer from December 2013 until February 2016.

28. Defendants Schelling and Palmin sometimes are referred to herein as the "Individual Defendants."

29. Each of the Individual Defendants:

a. directly participated in the management of the Company;

b. was directly involved in the day-to-day operations of the Company at the highest levels;

c. was privy to confidential proprietary information concerning the Company and its business and operations;

d. was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

e. was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

f. certified, pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), as to the Company's compliance with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and to the Company's quarterly and annual reports filed with the Securities and Exchange Commission during the Class Period as having fairly presented, in all material respects, the financial condition and results of operations of the Company;

g. was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and

h. approved or ratified these statements in violation of the federal securities laws.

30. Acer and the Individual Defendants are collectively referred to herein as "Defendants."

EXPERT DR. PHILLIP LAVIN

31. Prior to filing the Amended Complaint, Plaintiff engaged Dr. Phillip Lavin who is an expert in the area of biostatistics and in the FDA drug approval process.

32. Dr. Lavin is currently the Principal of a Boston-based biostatistics consulting practice, Lavin Consulting LLC, in business for 9 years and Executive Director for a not-for-profit research foundation, Boston Biostatistics Research Foundation, in business for 33 years. In 1983, Dr. Lavin founded and served as CEO for Boston Biostatistics, Inc., which became Averion in 2001, which grew into Averion International in 2006, which, upon a merger, became Aptiv Solutions in 2011, and which was purchased by ICON plc in 2014.

33. Dr. Lavin has over 40 years of experience in the field of biostatistics as a: (1) faculty member at Brown University (2 years), Harvard School of Public Health (7 years), and Harvard Medical School (21 more years); (2) an FDA Advisory panel member and Special Government Employee (33 years); and (3) an expert consultant to the pharmaceutical, biotechnology, and medical device industries (45 years).

34. Dr. Lavin's consulting work as a Lead Biostatistician has contributed to the approval of 64 FDA-regulated products to date through NDAs (New Drug Applications), BLAs (Biologics License Applications), and PMAs (Premarket Approvals), as well as a de novo and HDE (Humanitarian Device Exemptions). Dr. Lavin has also an elected Fellow of both the American Statistical Association and the Regulatory Affairs Professional Society.

35. Dr. Lavin has participated in the design, analysis, presentation, and publication of clinical studies since 1974, after receiving his Ph.D. in Applied Mathematics from Brown University in 1972. He has authored or co-authored 191 peer-reviewed publications and have been internationally recognized for his contributions to developing biomarkers, assessing prognostic

factors for oncology studies, using cardioplegia for open heart surgery, designing more efficient Phase II cancer studies by measuring tumor dimensions instead of binary response, modeling disease response and survival, optimizing kidney transplants, and developing classifiers to diagnose disease.

36. In addition, Dr. Lavin has provided expert support as a journal reviewer for *New England Journal of Medicine*, *Journal of the American Medical Association, Journal of Clinical Oncology, Radiology*, and others.

37. Dr. Lavin reviewed the published Ong Trial data, the portions of Acer's SEC filings that are relevant to this action, and the documents produced by Acer that are exhibits to this Third Amended Complaint.

38. Dr. Lavin's expert opinion is included in relevant portions of the substantive allegations below.

SUBSTANTIVE ALLEGATIONS

Background of Acer

39. Acer was founded in December 2013 and is headquartered in Newton, Massachusetts. Acer purports to be a development-stage pharmaceutical company focused on the acquisition, development, and commercialization of therapies for serious, rare and life-threatening diseases with significant unmet medical needs.

40. On September 19, 2017, the formerly private Acer ("Private Acer") completed a reverse merger with a publicly traded corporation formerly known as Opexa Therapeutics, Inc. ("Opexa"). Companies pursue reverse mergers when they are unable to gain the backing of an underwriter and investors for a conventional initial public offering ("IPO"). The reverse merger

here enabled Private Acer to "go public" quickly and access public capital while avoiding the more in-depth scrutiny of its finances and operations that comes with a traditional IPO.

41. As a result of the September 2017 reverse merger, Private Acer survived as a wholly-owned subsidiary of Opexa, and Opexa changed its name to "Acer Therapeutics Inc." and its trading symbol from "OPXA" to "ACER." The business that Private Acer had formerly conducted became the primary business conducted by Acer. Upon the closing of the reverse merger, the directors and the sole executive officer of Opexa resigned from their positions with Opexa, while the surviving company proceeded under the leadership of Private Acer's executive management team. On May 15, 2018, the Company changed its state of incorporation from Texas to Delaware. Following its reincorporation, the Company eliminated its holding company structure by merging the wholly-owned subsidiary Private Acer with and into the Company.

42. As of December 31, 2018, the Company had twenty-three full-time employees and no part-time employees. In addition, the Company employed a number of consultants or independent contractors.

43. Acer's product pipeline includes three clinical-stage candidates, including its most advanced product candidate, EDSIVO, as well as "ACER-001" and "osanetant." The Company has not generated any revenues from commercial sales of any of its current product candidates and has stated that its "ability to generate product revenue depends upon our ability to successfully identify, develop and commercialize these product candidates or other product candidates that we may develop, in-license or acquire in the future."

44. The Company has "not generated any revenue to date" and is "not profitable," having "incurred losses in each year since its inception in 2013." Substantially all of Acer's resources have been dedicated to the clinical development of its product candidates. Since Private

Acer's inception in December 2013, the Company spent approximately $28.5 million in research and development expenses through December 31, 2018. Of that amount, approximately $23.6 million was directly related to EDSIVO, while only approximately $4.2 million was directly related to ACER-001, one of the Company's other clinical-stage candidates.

45. In light of the substantial investment the Company has made in each of its products candidates, particularly EDSIVO (Acer's commercial name for celiprolol), Defendants have informed investors of the importance of obtaining FDA approval for each: "Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize our product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining approval from the FDA to market each product candidate." Not surprisingly, therefore, Defendants have warned investors that "our business will be substantially harmed" "if we are ultimately unable to obtain marketing approval for our product candidates."

Celiprolol is one of several similar beta-blockers prescribed off-label to treat vEDS.

46. vEDS is a rare and severe inherited connective tissue disorder caused by mutations in the collagen type III alpha I chain ("COL3A1") gene that affects approximately 2,000 to 5,000 people in the United States. It causes abnormal fragility in blood vessels, which can give rise to aneurysms, abnormal connections between blood vessels known as arteriovenous fistulas, arterial dissections, and spontaneous vascular ruptures, all of which can be potentially life-threatening.

47. There are no drugs approved for the treatment of vEDS in the United States or internationally. Certain members of the beta-blocker class of drugs, which are generally used to treat high blood pressure, are prescribed off-label as part of the management of vEDS. One such beta blocker is celiprolol, which has not been approved for any indication in the United States, but

has been approved for the treatment of hypertension in the European Union since 1984. Celiprolol, which is available as a low-cost generic in the European Union, is the primary drug used to treat vEDS patients in several European countries, including France. Although celiprolol is not approved by the FDA, patients can import it for personal use, including through online pharmacies.

48. Doctors frequently prescribe beta-blockers that are similar to celiprolol off-label to treat patients with vEDS in the United States. As the Marfan Foundation[3] explained in its June 25, 2019 "Statement on Celiprolol," "Patients should be aware that there are similar third generation beta-blockers, such as carvedilol, nebivolol, and labetalol, available in the US that are being prescribed off-label for [vEDS]." The Marfan Foundation further noted that "[b]oth carvedilol and labetalol are generic; therefore, they are very low in cost, and nebivolol will soon come off patent."

49. The Ehlers-Danlos Society also confirmed in its "Consensus statement from the Ehlers-Danlos Society and professional members of the vEDS community," published on August 9, 2019, that celiprolol is just one of several similar drugs used to treat vEDS:

> There is not enough evidence to know for sure whether people with vEDS should take celiprolol or another medication to manage blood pressure to try to change the rate of arterial complications. Some medical centers with expertise in vEDS use celiprolol for their patients. Other medical centers with expertise in vEDS use other blood pressure medications. Since there is not one clear best option right now, people with vEDS should talk with their health care provider to create a plan based on their personal medical history.

In preparation for its push to commercialize celiprolol in the United States under the name EDSIVO, Acer Acquired the rights to an old study of the drug instead of conducting new research.

50. In January 2015, the FDA approved Orphan Drug Exclusivity for EDSIVO. Orphan

[3] Marfan's Syndrome is in the same family of diseases as vEDS. The Marfan Foundation advances research for treatments that save lives and enhance quality of life for affected people. Its goal is to provide the latest and most accurate information, to educate patients, families, medical professionals and the general public about Marfan syndrome and related disorders.

Drug Exclusivity provides seven years of marketing exclusivity upon the approval of a drug intended to treat a rare condition. During that time, the FDA will not approve any other drug for the same indication unless it demonstrates clinical superiority.

51. The purpose of Orphan Drug Exclusivity is to promote the development of drugs to treat rare diseases. Acer, however, did not intend to conduct an additional clinical study to show the efficacy of EDSIVO. Instead, as stated in a December 13, 2016 press release, Acer signed an agreement with Assistance Publique—Hôpitaux de Paris, Hôpital Européen Georges Pompidou ("AP-HP") in Paris, France granting Private Acer exclusive rights to access and use data from a previously published study of celiprolol that only enrolled 53 participants.

52. In 2004, researchers at AP-HP published data on vEDS patients, observing that an abnormally low intima-media thickness generates a higher wall stress than in control subjects at the site of an elastic artery, which may increase the risk of arterial dissection and rupture. Based on this observation, the investigators aimed to assess the preventive effect of celiprolol for major cardiovascular events in patients with vEDS via a purported multicenter, prospective, randomized, open trial with blinded evaluation of clinical events in the Ong Trial. Results from the Ong Trial were published on October 30, 2010 in *The Lancet*, a weekly, peer-reviewed medical journal. The Ong Trial was funded by the French Ministry of Health, and the principal investigator for the study was Professor Pierre Boutouyrie.

53. As described in the Company's September 25, 2017 press release (the "September 25, 2017 Press Release"), Acer conducted a "retrospective source verified analysis" of the data from the Ong Trial instead of a new study.

54. Even though celiprolol is a cheap generic drug in the European Union and Acer did not conduct any new studies of the drug, analysts following Acer expected that if EDSIVO was

approved, Acer would be able to charge each patient more than $100,000 a year for the drug, in line with prices for other drugs with orphan status.

The FDA's Process for Reviewing Acer's NDA for EDSIVO

55. Every drug that has reached the U.S. market since 1938 has been the subject of an NDA, the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S. According to the FDA website,[4] "[t]he goals of the NDA are to provide enough information to permit FDA reviewer to reach the following key decisions:

a. whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks;

b. whether the drug's proposed labeling (package insert) is appropriate, and what it should contain; and

c. whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

56. "The documentation required in an NDA," according to the FDA website,[5] "is supposed to tell the drug's whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged."

57. According to Acer's Form 10-K for the fiscal year ended December 31, 2018 that it filed with the SEC on March 7, 2019 (the "2018 10-K"):

> The FDA is required to conduct a preliminary review of an NDA within the first 60 days after submission, before accepting it for

[4] *See* https://www.fda.gov/drugs/types-applications/new-drug-application-nda.

[5] *See id.*

> filing, to determine whether it is sufficiently complete to permit substantive review. The FDA may accept the NDA for filing, potentially refuse to file the NDA due to deficiencies but work with the applicant to rectify the deficiencies (in which case the NDA is filed upon resolution of the deficiencies) or refuse to file the NDA. The FDA must notify the applicant of a refusal to file a [sic] decision within 60 days after the original receipt date of the application. … Once an NDA is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act ("PDUFA") and the FDA's commitments under the current PDUFA Reauthorization Act, the FDA has a goal of reviewing and acting on 90% of standard non-priority NDA applications within ten months from the filing date of the NDA.

58. As Acer's statement indicates, an "in-depth substantive review" of an NDA does not take place until after an NDA is accepted for filing.

59. Expert Lavin, based on his extensive experience working for the FDA (33 years) and on NDAs (40 years), opined that the FDA acceptance of an NDA for filing is a weak indicator of its substantive merit and likelihood of success. According to him, to determine if it should accept an NDA for filing, the FDA only reviews an NDA for its completeness rather than for substantive content.

60. The PDUFA also provides for a "priority review" designation, which enables applicants that have submitted NDAs meeting certain criteria to receive a decision within 6 months, instead of the 10-month period under standard review. According to the FDA's website:[6]

> A Priority Review designation will direct overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.
>
> Significant improvement may be demonstrated by the following examples:

[6] *See* https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review.

> - evidence of increased effectiveness in treatment, prevention, or diagnosis of a condition;
> - elimination or substantial reduction of a treatment-limiting drug reaction;
> - documented enhancement of patient compliance that is expected to lead to an improvement in serious outcomes; or
> - evidence of safety and effectiveness in a new subpopulation.
>
> FDA decides on the review designation for every application. However, an applicant may expressly request priority review as described in the Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. It does not affect the length of the clinical trial period. FDA informs the applicant of a Priority Review designation within 60 days of the receipt of the original BLA, NDA, or efficacy supplement. Designation of a drug as "Priority" does not alter the scientific/medical standard for approval or the quality of evidence necessary.

61. In Expert Lavin's opinion, based on this extensive experience working for the FDA and on NDAs, the FDA generally grants priority review status based on theoretical considerations about whether a drug would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications, not based on the actual quality of the clinical trial data in an NDA. Accordingly, it is Expert Lavin's opinion that a grant of priority review status is not a strong indicator of the quality of the clinical trial data in an NDA.

62. After conducting its review centered on the drug candidate's safety and efficacy, the FDA then issues its decision by letter either approving the NDA or else rejecting or denying the NDA. If the FDA rejects or denies the NDA, it issues a CRL, which must, under 21 C.F.R. § 314.110(a)(1), contain "all of the specific deficiencies that the agency has identified":[7]

> The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective for its intended use and

[7] Note, however, that "[i]f FDA determines, after an application is filed or an abbreviated application is received, that the data submitted are inadequate to support approval, the agency might issue a complete response letter without first conducting required inspections and/or reviewing proposed product labeling." *Id.* § 314.110(a)(3).

> whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity. The FDA is required to refer an application for a novel drug to an advisory committee or explain why such referral was not made. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation in response to specific questions raised by the FDA, which may include whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.
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> After the FDA evaluates the NDA and conducts its inspections, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug subject to specific prescribing information for specific indications and, if applicable, specific post-approval requirements. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. After receiving a Complete Response Letter, the applicant must decide within twelve months (subject to extension), if it wants to resubmit the NDA addressing the deficiencies identified by the FDA in the Complete Response Letter, withdraw the NDA, or request an opportunity for a hearing to challenge the FDA's determination. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret data.

In advance of Defendants' September 30, 2015 meeting with the FDA about EDSIVO, Defendants asked the FDA if "no additional clinical studies will be needed for NDA approval?" and the FDA responded that approval based on a single study is "rare."

63. In Expert Lavin's opinion, it is standard practice for sponsors of a drug, such as Acer, to have numerous meetings with FDA officials prior to filing an NDA.

64. Sponsors send written questions to the FDA and the FDA responds to the questions in writing prior to the meeting. The FDA's official meeting minutes contain the sponsor's

questions, the FDA's written answers, and a summary of what occurred at the meeting.

65. Expert Lavin further opined that sponsors always maintain written notes and records from such meetings so that they are clear on the FDA's feedback and their path forward. All agreements reached between the FDA and a sponsor during a meeting are memorialized, and the minutes of meetings between a sponsor and the FDA are prepared by the FDA and sent to the sponsor. Accordingly, the sponsor knows well the outcome of a meeting, with the FDA's minutes reflecting the points discussed at the meeting and the outcome.

66. Acer hired Camargo Pharmaceutical Services, LLC, a consulting firm specializing in drug approval and commercialization, to assist with the development of EDSIVO.

67. Acer's first meeting with the FDA concerning EDSIVO was a Pre-IND Type B[8] Meeting that occurred on September 30, 2015. On October 13, 2015, The FDA sent Acer a letter with a copy of the "Memorandum of Meeting Minutes" it had prepared for the September 30, 2015 meeting attached. The copy of the letter and meeting minutes that Defendants produced from their files to Plaintiff is attached as **Exhibit 1**.

68. The FDA's October 13, 2015 letter to Acer stated "A copy of the official minutes of the meeting is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes." (emphasis in original).

69. The September 30, 2015 meeting minutes stated that Defendant Schelling and Ben Dewees ("Dewees"), Acer's Vice President of Regulatory and Manufacturing, both attended the meeting.

70. The September 30, 2015 meeting minutes showed that one of the questions that Acer sent to the FDA prior to the meeting was whether any additional clinical studies were needed

[8] An explanation of the types of meetings that the FDA holds with sponsors can be found here: https://www.fda.gov/drugs/data-standards-manual-monographs/industry-meeting-type.

for the ***approval*** of EDSIVO other than the already completed Ong Trial: "Does the Agency agree that the published literature provides sufficient efficacy support for celiprolol in the treatment of vEDS, and ***that no additional clinical studies will be needed for NDA approval***?" (Exhibit 1 at ACER_0002207 (emphasis added).) ***The FDA did not agree.*** Instead, the FDA responded to the question by stating that it was possible that the Ong Trial could support the filing of an NDA, but that ***approval based on a single study was rare***: "The literature ***may*** support filing an NDA. ***We should note that approval based solely on the published report of a single study is rare.***" (*Id.* (emphasis added).)

71. Accordingly, since at least October 30, 2015, Defendants knew that the FDA was very unlikely to approve EDSIVO without an additional clinical study.

When Acer met with the FDA again on May 17, 2017, the FDA independently raised concerns that the results of the Ong Trial were biased by a randomization imbalance between the celiprolol and placebo groups and that the results were not statistically significant due to the use of flawed interim analyses.

72. Acer next met with the FDA about EDSIVO at a Type C Guidance meeting that took place on May 18, 2017. On June 15, 2017, the FDA sent Acer a letter with a copy of the "Memorandum of Meeting Minutes" it prepared for the May 18, 2017 meeting attached. The copy of the letter and meeting minutes that Defendants produced from their files to Plaintiff is attached as **Exhibit 2**.

73. The FDA's June 15, 2017 letter to Acer stated "A copy of the official minutes of the meeting/telecon is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes."

74. The May 18, 2017 meeting minutes stated that Defendant Schelling, Dewees, and Robert Steiner, MD, Chief Medical Officer of Acer, attended the meeting.

75. The May 18, 2017 meeting minutes started with a "Background" section stated that

"Acer Therapeutics ('Acer') has previously met with FDA to discuss submitting a 505(b)(2) NDA for approval to treat Vascular Ehlers-Danlos Syndrome (vEDS)." (Exhibit 2 at ACER_0002335.) The Background section made no mention of any prior agreement between Acer and the FDA.

76. The May 18, 2017 meeting minutes further show that, although Acer did not present the FDA with any questions about whether the Ong Trial was an adequate and well controlled study,[9] the FDA independently raised concerns about its adequacy. The FDA indicated it was concerned about the Ong Trial because: (1) a randomization imbalance in major diagnostic criteria between and celiprolol and placebo groups may have biased the study in favor of celiprolol and (2) the Ong Trial did not have statistically significant results because it used improperly conducted interim analyses of efficacy, which led to the Trial's premature termination:

> ACER should address the following concerns we identified in the publication that reports the results of the celiprolol study in vEDS patients:
>
> 1) ***Randomization imbalance***: It appears to us that there was an imbalance at baseline between the celiprolol subjects and the placebo subjects in the frequency of major diagnostic criteria, which reflect the risk for arterial rupture that favored celiprolol over placebo. ***If true, the results of the study were potentially biased in favor of celiprolol***….
>
> 2) Interim analyses: Multiple interim analyses were conducted throughout the course of the trial. ***We are concerned that alpha was not properly adjusted to account for these multiple analyses.*** [10]

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[9] *See* 21 C.F.R. § 314.126(b), which provides that an "adequate and well-controlled study" is characterized by, among other things, the use of "a design that permits a valid comparison with a control to provide a quantitative assessment of drug effect," "the method of selection of subjects provides adequate assurance that they have the disease or condition being studied, or evidence of susceptibility and exposure to the condition against which prophylaxis is directed," "the method of assigning patients to treatment and control groups minimizes bias and is intended to assure comparability of the groups with respect to pertinent variables," and "adequate measures are taken to minimize bias on the part of the subjects, observers, and analysts of the data."

[10] "Alpha" is the targeted level corresponding to statistical significance.

(Exhibit 2 at ACER_0002339- ACER_0002340 (emphasis added).)

77. When discussing the "randomization imbalance" in the Ong Trial, the FDA was referring to multiple differences between the celiprolol and control groups that biased the results of the Ong Trial. *First,* during the course of the Ong Trial, researchers learned that more than one-third (20 out of 53) of the participants did not have a COL3A1 gene mutation, which is the cause of vEDS. The absence of such a genetic mutation was not evenly distributed between the celiprolol arm of the study and the control group. While 12 of the 25 patients in the celiprolol arm did not have a proven COL3A1 mutation, only 8 out of the 28 patients in the control group did not have the proven genetic mutation. *Second*, 11 (44%) members of the celiprolol group and 16 (57%) members of control group had a family history of vEDS. *Third*, 2 (8%) members of the celiprolol group and 6 (21%) members of control group had a personal and 1st degree relative with a history of arterial rupture or dissection, uterine or intestinal rupture. *Fourth*, the control group was also sicker than the celiprolol group based on multiple phenotypic characteristics, including: acrogeria (21 in control group vs 15 in celiprolol group), hypermobility of joints (23 vs 17), tendon rupture (6 vs 2), lower limb varicosity (11 vs 6), and bruising (25 vs 18).

78. Expert Lavin explained that because of the imbalance of participants with the COL3A1 gene mutation in the celiprolol and placebo group, the celiprolol group had a 19.4% head start towards event-free survival, which is highly material and equates to a 5-event advantage for the celiprolol group. Given that an 8-event advantage reaches statistical significance, any scenario among the 13 celiprolol participants and the 20 control participants with the mutation where there are just 3 fewer events in the mutation-present treatment group will result in a statistically significant event-free survival advantage. Accordingly, this means that the treatment group had a 5-event head start over the control group towards reaching statistical significance (8-event advantage).

79. In its statement concerning the "Interim analyses" of the Ong Trial, the FDA was expressing concern that the Ong Trial did not adjust the p-value (or level of significance) necessary to achieve statistical significance to compensate for the multiple interim analyses that researchers conducted prior to the time that the original trial plan called for the Trial to conclude. Conducting multiple interim analyses introduces additional error into the results of a clinical trial because repeatedly looking at the data increases the chance that an indication of efficacy could be the result of random chance. This was an especially serious problem because the Ong Trial was terminated early based on those improperly conducted interim analyses, which was compounded because the results were not statistically significant when the study was terminated nor at any of the preceding interim analyses. The Ong Trial was terminated after only enrolling 53 patients, even though researchers had intended to enroll 100 patients and many of the enrolled patients were not monitored for the full 5-year duration that the original trial plan called for.

Acer raises money from investors by claiming that the FDA "agreed" that "additional clinical development" beyond the Ong Trial was "not needed" and makes other misrepresentations about its meetings with the FDA and the Ong Trial.

80. Shortly after the completion of its reverse merger in September 2017, Acer used its new status as a public company to raise money from investors in a secondary public offering of stock.

81. Acer announced results from its retrospective source verified analysis of the Ong Trial data in the September 25, 2017 Press Release. It touted the Ong Trial without disclosing the FDA's warnings that NDA approval based on a single study was rare and that the Ong Trial had a randomization imbalance and used improperly conducted interim analyses. The September 25, 2017 Press Release stated that "Acer…today announced positive results from the pivotal clinical trial of EDSIVO™ (celiprolol)" and that the Ong Trial had "achieved statistical significance." It

also quoted Defendant Schelling as saying that "[w]e continue to successfully rapidly advance our lead product candidate, EDSIVO…" and that the Ong Trial was a "robust clinical study."

82. Defendants continued to mislead investors about the Ong Trial in a presentation that Defendant Schelling delivered at the Cantor Fitzgerald Global Healthcare Conference in New York City on September 26, 2017 (the "September 26, 2017 Presentation"). On the same day, Acer filed a Form 8-K with the SEC, signed by Defendant Palmin, that attached the September 26, 2017 Presentation. The September 26, 2017 Presentation said that the Ong Trial showed a "statistically-significant improvement in event-free survival" and featured a slide about the Ong Trial that was entitled "EDSIVO™ Statistically Significant Efficacy." It further asserted that "Important phenotype characteristics [were] equally balanced between celiprolol and control" in the Ong Trial. According to press releases issued by Acer, Defendant Schelling also gave investor presentations at the 2018 Biotech Showcase Conference in San Francisco, California, the LEERINK Partners 7th Annual Global Healthcare Conference in New York City, and the 30th Annual ROTH Conference in Laguna Niguel, California on January 10, 2018, February 15, 2018, and March 13, 2018, respectively.

83. On November 14, 2017 Acer filed a Post-Effective Amendment to Form S-3 Registration Statement that included a preliminary prospectus (the "November 14, 2017 Preliminary Prospectus"). The Company filed a Notice of Effectiveness with the SEC on November 21, 2017 making that post-effective amendment to its registration statement effective. After the market closed on December 11, 2017, Acer announced a secondary public offering of common stock. On the same day, Acer filed the final version of the November 14, 2017 Preliminary Prospectus, which was dated November 21, 2017 (the "November 21, 2017 Prospectus"), and a Preliminary Prospectus Supplement (the "December 11, 2017 Preliminary

Prospectus Supplement") with the SEC. Acer filed its final prospectus supplement on December 12, 2017 (the "December 12, 2017 Prospectus Supplement"). In each of the November 14, 2017 Preliminary Prospectus, November 21, 2017 Prospectus, the December 11, 2017 Preliminary Prospectus Supplement, and December 12, 2017 Prospectus Supplement (collectively, the "December 2017 Offering Documents"), Defendants misrepresented that Acer and the FDA had reached an agreement that Acer would not need to conduct any clinical development beyond the already-completed Ong Trial. Defendants stated that at a September 2015 meeting at which Acer "met with the FDA to discuss the existing clinical data for EDSIVO," "***the FDA agreed that additional clinical development is not needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS" (emphasis added).

84. Defendants' statement completely misrepresented what occurred at Acer's September 30, 2015 meeting with the FDA. Defendants asked if "the Agency agree[d]…that no additional clinical studies will be needed for NDA ***approval***?" and the FDA ***specifically did not agree***. (Exhibit 1 at ACER_0002207 (emphasis added).) Instead, it stated that ***that "approval based solely on the published report of a single study is rare***." (*Id.*(emphasis added).)

85. Based on this misrepresentation, the Company raised gross proceeds of $12.56 million from its December 2017 offering.

86. On March 7, 2018, the Company filed with the SEC its annual report on Form 10-K for the fiscal year ended December 31, 2017 (the "2017 10-K"). In the 2017 10-K, Defendants continued to assure investors that the FDA would approve EDSIVO based on the Ong Trial: "In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. ***At that meeting, the FDA agreed that an additional clinical trial is not likely needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS" (emphasis added).

87. Notably, the 2017 10-K differed from the documents for the December 2017 Offering Documents in that Acer slightly revised its description of the FDA meeting. Instead of unambiguously stating that "additional clinical development" was "not needed," Acer limited the statement in the 2017 10-K to an "an additional clinical ***trial***" instead of the more general term "***development***" and stated that it was "not ***likely*** needed."

88. Several things are clear from Defendants revision of their description of Acer's agreement with the FDA at the September 2015 meeting. *First*, given that Acer altered the statement without explanation and without alerting investors to the change, the statement was clearly intended to continue to assure investors that the FDA had agreed to approve EDSIVO based on the Ong Trial and to generally affirm Acer's earlier, more definitive statement. *Second*, the first statement, in which Acer unambiguously stated that the FDA "agreed that additional clinical development is not needed" was false. If the statement had been true, there would have been no need to revise it to add "likely" and to change "development" to "trial." *Third*, the fact that Defendants revised the initial statement about the meeting shows that they knew it was false. They, however, did not advise investors of their misstatement. Instead, ***after their successful stock offering***, Defendants subtly revised the statement so that it was still false and misleading, but they would have a little more leeway if investors ever found out that Acer did not actually have an agreement with the FDA (which they did when the FDA rejected EDSIVO's NDA).

89. The 2017 10-K also contained a misleading summary of the Acer's May 2017 meeting with the FDA. The 2017 10-K stated that at the May 2017 meeting, "the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing." This statement was extremely misleading because the FDA criticisms were not limited to guidance on the presentation of the data. Instead, the FDA's

criticisms about the Ong Trial's randomization imbalance and improper interim analyses and early termination identified serious flaws in how the Ong Trial was originally conducted that could not be remedied after-the-fact.

90. Finally, despite the FDA's warning about the Ong Trial's randomization imbalance, the 2017 10-K stated that, in the Ong Trial, "Patients were randomly assigned to a five-year intervention, receiving either celiprolol or no treatment, ***with important phenotype characteristics equally balanced between the celiprolol group and the control group***." (emphasis added.)

In two meetings in June 2018, the FDA again refused to agree that the Ong Trial was sufficient to support the efficacy of EDSIVO and again expressed concerns about the Trial's randomization imbalance and flawed interim analyses.

91. Acer's next two meetings with the FDA concerning EDSIVO took place in June 2018. Acer and the FDA had a Type C Guidance meeting on June 14, 2018 and a Type B Pre-NDA meeting on June 28, 2018.

92. As is standard practice for drug sponsors, Acer prepared briefing packages that it sent to the FDA prior to each meeting. Acer sent the briefing packages for the June 14, 2018 and June 28, 2018 meetings to the FDA on May 3, 2018 and May 29, 2018, respectively. Excerpts of the copies of the briefing packages that Defendants produced from their files to Plaintiff are attached as **Exhibits 3 and 4**.

93. Both briefing packages contained sections entitled "Brief History of Development," that described Acer's September 30, 2015 meeting with the FDA. Unlike in Acer's public filings, the descriptions of the September 30, 2015 meeting that Acer submitted to the FDA ***did not mention an agreement between Acer and the FDA***. **(**Exhibit 3 at ACER_0002408-ACER_0002409 and Exhibit 4 at ACER_0002443.)

94. On July 12, 2018, the FDA sent Acer a letter with a copy of the "Memorandum of Meeting Minutes" it prepared for the June 14, 2018 meeting attached. The copy of the letter and

meeting minutes that Defendants produced from their files to Plaintiff is attached as **Exhibit 5**.

95. The FDA's July 12, 2018 letter to Acer stated that one of the purposes of the June 14, 2018 meeting was to "review and discuss the results of the BBEST study published in The Lancet by Ong, et al 2010" (the "BBEST" study is the name the FDA used for the Ong Trial) and to "Address three topics identified in The Lancet publication," two of which were "Randomization imbalance and method of randomization" and "Interim analyses." (Exhibit 5 at ACER_0002552.) The letter further stated that "[a] copy of the official minutes of the meeting is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes." (*Id.*)

96. The June 14, 2018 meeting minutes stated that Defendant Schelling and William T. Andrews ("Andrews"), MD, Chief Medical Officer of Acer, attended the meeting.

97. Additionally, from the June 14, 2018 meeting minutes it appears that Acer was no longer working with Camargo Pharmaceutical Services, LLC on EDSIVO's NDA and was instead working with Williamson BioPharma Consulting, LLC.

98. The June 14, 2018 meeting minutes show that, even though it had been more than a year since the May 18, 2017 meeting, Acer had not been able to alleviate the problems the FDA identified about the Ong Trial.

99. Defendants asked if the FDA agreed that a covariate analysis adjusting for the presence or absence of the three major diagnostic criteria would address its concerns that the randomization imbalance created bias in the Ong Trial:

> ***Question 1:*** ***Randomization Imbalance and Method of Randomization***
> *Does the Agency agree that the covariate analysis adjusting for the presence or absence of the three major diagnostic criteria would appropriately address the Agency's question regarding potential bias or effect on the primary efficacy outcomes?*

(Exhibit 5 at ACER_0002555 (emphasis in original).)

100. FDA responded that Acer had not provided them with enough information and noted that the Ong Trial had a small sample size:

> ***FDA Response to Question 1:***
> We need more information before we can provide agreement on your covariate adjustment. To facilitate agreement on the baseline covariates, we recommend using a panel of outside experts in the treatment of vascular Ehlers-Danlos Syndrome to select a set of prognostic covariates to include in your adjusted Cox proportional hazards model. In addition, you must submit your statistical analysis plan for review. Plan to include a stratified permutation test of time to primary efficacy outcome ***because of the small sample size in BBEST.***

(*Id.* at ACER_0002556 (emphasis added).)

101. The June 14, 2018 meeting minutes further stated that the FDA told Defendants during the meeting discussion that there was an imbalance in patients that presented with bruising between the celiprolol and control groups in the Ong Trial and asked if an adjustment had been made for it or the imbalance of the COL3A1 gene mutation:

> The Division noted that bruising was a major Villefranche criteria[11] for vEDS and that there was an imbalance for this criterion between the two groups (72% celiprolol vs 89% control). The Division asked whether an adjustment was made for bruising or the genetic criteria.

(*Id.*)

102. Regarding the interim analyses of the Ong Trial, the June 14, 2018 meeting minutes showed that Defendants asked the FDA if it "agree[d]" that Acer did not have to adjust the "final outcome analysis" of the Ong Trial based on the fact it was terminated early:

> ***Question 2:*** ***Interim Analyses***
> *Does the Agency agree that adjustment for Type I error in the final outcome analysis was not required in the original BBEST study*

[11] The Villefranche criteria are a set of physical characteristics that are used to aid in the diagnosis of EDS patients.

> *given that the study was not stopped due to efficacy as evidenced by crossing of a priori defined boundaries?*

(*Id.*)

103. Unsurprisingly, given that the FDA had told Acer that an adjustment was needed more than a year ago, at the May 18, 2017 meeting, ***the FDA did not agree***:

> ***FDA Response to Question 2:***
> ***No, we do not agree.*** It is our understanding that BBEST was stopped early "because significant differences were recorded between the two groups in the whole population after 64 months" (Ong 2010 article in *The Lancet*). ***In this situation, Whitehead 2004 states that p-values obtained from a conventional analysis are invalid*** and recommends that an adjusted p-value be reported. ***Regardless of the reason for study termination of BBEST, the unblinded looks at the data may have increased the type I error rate.***

(*Id.* (emphasis added).)

104. The June 14, 2018 meeting minutes further stated that during the discussion about the interim analyses issue, Defendants admitted that they did not even have documentation of the original interim analyses conducted on the Ong Trial:

> ***The Sponsor also explained that they do not have the documentation of the previous interim analyses***, but the DMC [Data Monitoring Committee] meeting minutes are available. Because the final data are available, the interim analyses and the final analysis will be recalculated. The Division asked the Sponsor to provide the minutes from the meeting with DMC at the time of NDA submission and to calculate the nominal alpha for each interim analysis based on the DMC meeting minutes that capture when the interim analyses were performed.

(*Id.* at ACER_0002557 (emphasis added).)

105. On July 26, 2018, The FDA sent Acer a letter with a copy of the "Memorandum of Meeting Minutes" it prepared for the June 28, 2018 meeting attached. The copy of the letter and meeting minutes that Defendants produced from their files to Plaintiff is attached as **Exhibit 6**.

106. As with the June 14, 2018 meeting, the June 28, 2018 meeting minutes show that

Defendant Schelling and Andrews attended the meeting.

107. The FDA's July 26, 2018 letter stated that "[a] copy of the official minutes of the meeting is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes."

108. The June 28, 2018 meeting minutes show that Defendants again, as they did in the September 30, 2015 meeting, asked if the FDA agreed that the Ong Trial was sufficient to support the efficacy of celiprolol for treatment of vEDS patients with a confirmed COL3A1 mutation:

> **Question 13**: Does the Agency agree that the source-verified data from the BBEST study, which corroborates the results as reported in The Lancet (Ong et al. 2010)…support the…efficacy of celiprolol for treatment of vEDS patients with a confirmed COL3Al mutation?

(Exhibit 6 at ACER_0002613.)

109. The FDA ***did not agree*****,** stating that it could only decide whether the data was sufficient to support ***filing or efficacy*** after its substantive review of EDSIVO's NDA:

> ***FDA Response to Question 13:***
> ***We can only decide on the adequacy of the data to support filing, efficacy and safety after our review.***

(*Id.* (emphasis added).)

Following the June 2018 meetings with the FDA, Defendants continue to make misleading statements, including stating again that "the FDA agreed that an additional clinical trial is not likely needed."

110. On June 29, 2018, Acer filed a Form 8-K with the SEC that attached an updated Investor Presentation, (the "June 29, 2018 Presentation"). The June 29, 2018 Presentation did not disclose the concerns that the FDA expressed in the June meetings that the Ong Trial was not sufficient to show the efficacy of celiprolol. Instead the Presentation stated that EDSIVO showed "statistically-significant improvement in event-free survival" and featured a slide about the Ong Trial that was entitled "EDSIVO™ Statistically Significant Efficacy." It further asserted that

"Important phenotype characteristics [were] equally balanced between celiprolol and control" in the Ong Trial despite the fact that the FDA had specifically pointed out that there was an imbalance between the two groups in bruising and genetic criteria. According to press releases issued by Acer, Acer's management team made investor presentations at the H.C. Wainwright 20th Annual Global Investment Conference in New York City, the 2018 Cantor Fitzgerald Global Healthcare Conference in New York City, and the Evercore ISI HealthConX Conference in Boston, Massachusetts on September 5, 2018, October 3, 2018, and November 28, 2018, respectively.

111. In a Preliminary Prospectus Supplement filed with the SEC on July 31, 2018, and in a Prospectus Supplement filed with the SEC on August 1, 2018 (the "August 2018 Offering Documents") for another secondary offering, Defendants repeated again that at the September 2015 meeting "the FDA agreed that an additional clinical trial is not likely needed" for EDSIVO. As alleged above, the FDA did not make any such agreement during the September 2015 meeting. This statement was also misleading because, according to the June 28, 2018 meeting minutes, Acer again asked the FDA to agree that the Ong Trial supported the efficacy of celiprolol and the FDA refused to agree that the Ong Trial was sufficient to support ***filing*** of EDSIVO's NDA or to show EDSIVO's ***efficacy***.

112. The August 2018 Offering Documents also repeated the misleading statement about the May 2017 FDA meeting from the 2017 10-K and stated that Acer held the June 2018 meetings with the FDA without disclosing anything about the FDA's escalating concerns about the Ong Trial.

113. The August 2018 offering documents also continued to assert that the "important phenotype characteristics [were] equally balanced between the celiprolol group and the control group" in the Ong Trial, when the FDA had specifically told Defendants that it disagreed.

While EDSIVO's NDA was under submission, Acer continued to signal to the market that the FDA had agreed no additional clinical trials were needed even though the FDA continued to indicate that the Ong Trial was not sufficient for approval.

114. On October 29, 2018, Defendants issued a press release (the "October 29, 2018 Press Release") announcing that Acer had submitted its NDA for EDSIVO. Defendants also reported in the October 29, 2018 Press Release that the Company had "requested Priority Review, which if granted, could result in a six-month review period," while noting that "Priority Review is a designation given to drugs that offer a significant improvement in treatment or provide treatment where no satisfactory alternative therapy exists." The October 29, 2018 Press Release quoted Dr. William Andrews, Acer's chief medical officer, as stating: "We now look forward to continuing to work with the FDA as they review our NDA, with hopes to make EDSIVO available as quickly as possible in the U.S."

115. In a letter dated December 21, 2018, the FDA informed Acer it had completed its "filing review" of the NDA for EDSIVO and "determined that your application is sufficiently complete to permit a substantive review" and, therefore, the NDA was "considered filed" (the "December 21, 2018 Letter"). The copy of the December 21, 2018 Letter that Defendants produced from their files to Plaintiff is attached as **Exhibit 7**.

116. Despite stating that Acer's NDA for EDSIVO was complete, the FDA's December 21, 2018 Letter continued to warn that the Ong Trial was not sufficient to show the efficacy of EDSIVO because of its randomization imbalance, improperly conducted interim analyses, and premature termination:

> 1) Randomization Imbalance: Given the imbalance in the major diagnostic criteria and the COL3A1 genetic mutation in the treatment groups, it is unclear whether these treatment groups are comparable.
>
> 2) Interim Analyses: Multiple interim analyses were conducted without preplanned alpha spending.

…

> 4) Premature termination: The study was terminated when approximately 50% of the planned enrollment was complete. The decision to terminate the trial appears to have been made shortly after 2 events were reported in the control arm.

117. On December 26, 2018, Defendants issued a press release (the "December 26, 2018 Press Release") announcing that the FDA had accepted for review the Company's NDA for EDSIVO. The December 26, 2018 Press Release further noted that "[t]he FDA also granted a priority review of the NDA and assigned a Prescription Drug User Fee Act (PDUFA) target action date of June 25, 2019. Priority review is a designation granted by the FDA to accelerate the review process for drugs that offer a significant improvement in treatment or provide treatment where no satisfactory alternative therapy exists." In addition, the December 26, 2018 Press Release quoted Defendant Schelling as stating: "[w]e continue to accelerate our pre-commercial activities supporting the potential U.S. launch of EDSIVO for the treatment of vEDS if it is approved by the FDA." The December 26, 2018 Press Release did not disclose anything about the FDA's continued warnings about serious flaws in the Ong Trial.

118. On January 7, 2019, Acer again filed a Form 8-K with the SEC that attached an updated Investor Presentation, (the "January 7, 2019 Presentation"). Despite the FDA's continued warnings about the Ong Trial's randomization imbalance and improperly conducted interim analysis and premature termination, Acer stated in the January 7, 2019 Presentation that Acer's product candidates had a "de-risked profile" and again stated that the Ong Trial showed "statistically significant efficacy." According to press releases issued by Acer, Acer's management team made investor presentations at the 2019 San Francisco Biotech Showcase in San Francisco, California and the 2019 ROTH Conference in Laguna Niguel, California on January 10, 2019 and March 18, 2019, respectively.

119. On March 6, 2019, the FDA sent Acer a letter with the minutes of the "mid-cycle communication" teleconference that the FDA had with Acer on February 11, 2019 attached. The copy of the letter and minutes that Defendants produced from their files to Plaintiff is attached as **Exhibit 8**.

120. The minutes of the February 11, 2019 meeting state that Defendant Schelling, Andrews, and Stacey Bain, Acer's Vice President, Clinical Operations, attended it.

121. The February 11, 2019 meeting minutes show that based on a preliminary analysis of EDSIVO's NDA, the FDA had concluded that Ong Trial was not sufficient to show the efficacy of EDSIVO against vEDS.

122. The FDA stated that it had used the Whitehead triangulation test to ascertain whether the Ong Trial showed the efficacy of EDSIVO and concluded that ***efficacy was inconclusive***:

> Inconclusive efficacy. The Whitehead triangulation test was used to ascertain efficacy during the performance of multiple pre-planned interim analyses. The original stopping boundaries are unknown. ***Stopping boundaries that we estimated were never crossed during 4 interim analyses, although the trial was terminated at 50% of the planned enrollment by parties unblinded to endpoint distribution between the arms of BBEST at the time of termination, thus introducing potential bias.***

(Exhibit 8 at ACER_0002653 (emphasis added).) [12]

123. The February 11, 2019 meeting minutes further stated that Acer asked the FDA to use a revised version of the Whitehead analysis, but FDA Statistician John Lawrence rejected that request:

> Dr. Lawrence did not agree with Acer's suggestion regarding a revised Whitehead analysis based on the smaller N in the study. Dr. Lawrence indicated that he would perform an analysis using a

[12] The "stopping boundaries" are the boundaries that the Ong Trial needed to cross to achieve statistical significance under the Whitehead test.

> strategy published by John Whitehead, which is suitable for this type of monitoring.

(*Id.*)

124. The FDA's use of the Whitehead test could not have come as a surprise to Acer given that the June 14, 2018 meeting minutes indicated that the FDA told Acer it would use the Whitehead test to evaluate that Ong Trial's interim analyses.

125. The February 11, 2019 meeting minutes also show that the FDA stated that the Ong Trial had "[b]aseline imbalances," including significant differences between the phenotypic presentations of the celiprolol and control groups, that "impact[ed] statistical significance":

> Baseline imbalances impacting statistical significance.
> ***There were numerous imbalances suggesting the no-beta-blocker arm was sicker at baseline than the celiprolol arm: 1) family history of vEDS (16 vs 11); 2) personal and 1st degree relative with a history of arterial rupture or dissection, uterine or intestinal rupture (6 vs 2); 3) phenotypic presentation: acrogeria (21 vs 15), hypermobility of joints (23 vs 17), tendon rupture (6 vs 2), lower limb varicosity (11 vs 6), bruising (25 vs 18); and 4) reported COL3A1 genetic defect (20 vs 13). An analysis was performed to adjust for the presence or absence of three protocol-defined major diagnostic criteria: 1) personal/family history of arterial rupture; 2) history of hollow organ rupture; and 3) COL3A1 gene mutation.*** The analysis demonstrated that the 95% confidence interval for the hazard ratio crossed unity for each adjustment, suggesting no impact from imbalances of three evaluated diagnostic criteria. However, the p-value from the stratified log-rank test was 0.098, consistent with the permutation test p-value of 0.11, ***showing a loss of statistical significance by controlling for the effects of the diagnostic criteria.***

(*Id.* (emphasis added).)

126. Acer's 2018 10-K, which the Company filed with the SEC on March 7, 2019, did not disclose anything about the FDA's negative statements that the Ong Trial showed "Inconclusive efficacy" and was not statistically significant. Instead the 2018 10-K stated that Acer's product candidates had a "de-risked profile" and touted the facts that EDSIVO had been

granted priority review by the FDA and that the FDA had targeted June 25, 2019 as the date it would make a decision on EDSIVO's NDA. (emphasis added).

127. The 2018 10-K further stated that the important phenotype characteristics in the Ong Trial were "equally balanced between the celiprolol group and control group" even though the FDA had specifically told Acer that "numerous imbalances," including in phenotype, had caused the Ong Trial to lose statistical significance.

128. On March 29, 2019, the FDA sent Acer a background package for Acer's "Late Cycle Meeting" with the FDA, which was scheduled for April 9, 2019. The copy of the Late Cycle Meeting background package that Defendants produced from their files to Plaintiff is attached as **Exhibit 9**.

129. In the Late Cycle Meeting background package, the FDA noted that the Ong Trial served as the sole trial supporting the use of celiprolol in vEDS patients and that it had several defects:

> The BBEST study served as the sole trial to support the use of celiprolol for the treatment of vascular (type IV) Ehlers Danlos Syndrome. Several liabilities were identified and explained in the mid-cycle communiation [sic] dated 06 March 2019.

(Exhibit 9 at ACER_0002659.)

130. The Late Cycle Meeting background package further stated that the FDA performed interim analyses of the Ong Trial based on the Whitehead triangulation test and concluded the efficacy results were inconclusive:

> **Inconclusive efficacy results**
> Multiple interim analyses were performed with alpha adjustments based on the Whitehead triangulation test. The original stopping boundaries were unknown. New stopping boundaries were estimated. The stopping boundaries were not crossed at any of 4 interim analyses, but the trial was terminated with only 50% of planned enrollment and with full knowledge of the nominal

outcome.

(*Id.*)

131. The FDA also reiterated in the Late Cycle Meeting background package that the Ong Trial had baseline imbalances in risk factors between the celiprolol arm and further stated that ***Acer's own analysis based on three diagnostic criteria rendered the treatment effect of celiprolol non-significant***:

> **Baseline imbalances in risk factors**
> There were baseline imbalances in the number of subjects between the no beta blocker aim vs the celiprolol arm of the BBEST trial for: 1) family history of vEDS (*16 vs 11*); 2) personal and 1st degree relative with a history of arterial rupture or dissection and uterine or intestinal rupture (*6 vs 2*); 3) phenotypic presentation: acrogeria (*21 vs 15*), hypermobility of joints (*23 vs 17*), tendon rupture (*6 vs 2*), lower limb varicosity (*11 vs 6*), bruising (*25 vs 18*); and 4) the reported COL3A1 genetic defect (*20 vs 13*). ***Your analysis adjusting for three protocol-defined major diagnostic criteria—personal/family history of arterial rupture, history of hollow organ rupture, or COL3A1 gene mutation—renders the treatment effect non-significant, as does a permutation test.***

(*Id.* at ACER_0002659- ACER_0002660 (bold and italics added).)

132. On April 5, 2019, Acer again filed a Form 8-K with the SEC that attached an updated Investor Presentation (the "April 5, 2019 Presentation"). Despite the fact the FDA stated that the Ong Trial had "inconclusive efficacy results" and the "treatment effect" was non-significant," the April 5, 2019 Presentation stated that Acer's product candidates had a "de-risked profile" and that EDSIVO showed "statistically-significant improvement" and "Statistically Significant Efficacy." According to press releases issued by Acer, Acer's management team made investor presentations at the Needham & Company 18th Annual Healthcare Conference in New York City, the 2019 UBS Global Healthcare Conference in New York City, the William Blair 2019 Growth Stock Conference in Chicago, Illinois, the Jefferies 2019 Healthcare Conference in New York City, and the Raymond James Life Sciences & MedTech Conference in New York City

on April 10, 2019, May 21, 2019, June 5, 2019, June 6, 2019, and June 19, 2019, respectively.

133. On May 6, 2019, The FDA sent Acer a letter with a copy of the "Memorandum of Late-Cycle Meeting Minutes" it prepared based on the April 9, 2019 Late-Cycle meeting attached. The copy of the letter and meeting minutes that Defendants produced from their files to Plaintiff is attached as **Exhibit 10**.

134. The May 6, 2019 letter stated that "[a] copy of the official minutes of the LCM is enclosed for your information. Please notify us of any significant differences in understanding regarding the meeting outcomes."

135. The April 9, 2019 Late Cycle Meeting minutes stated that Defendant Schelling and Andrews attended the meeting and reiterated the statements in the Late Cycle Meeting background package, quoted in Paragraphs 130-131. (Exhibit 10 at ACER_0002666-ACER_0002667.)

136. April 9, 2019 Late Cycle meeting minutes further stated that during the meeting Acer admitted that the Ong Trial was stopped before it showed the efficacy of celiprolol: "***The Applicant agreed*** with the Division's conclusions that the stopping boundaries were not crossed and the trial was terminated prematurely." (*Id.* at ACER_0002666 (emphasis added).)

137. The April 9, 2019 Late Cycle Meeting Minutes also stated that, during the meeting, Acer argued that baseline imbalances in arterial rupture, hollow-organ rupture, and COL3A1 gene mutation did not affect the outcome of the Ong Trial. In response, the FDA reiterated that baseline imbalances rendered the Ong Trial statistically insignificant:

> The Division reiterated that when adjusting for baseline imbalances, the p-value of 0.02 increased to 0.09 by the stratified log-rank test and to 0.11 by the stratified permutation test. The p-value for the primary endpoint was also not adjusted for the multiple interim analyses, and the boundary was not crossed.

(*Id.* at ACER_0002667.)

138. Despite the fact that the FDA indicated to Acer during the April 9, 2019 Late Cycle

Meeting that the Ong Trial did not show that EDSIVO was effective in vEDS patients and it was, therefore, almost certain to reject EDSIVO's NDA, Acer put out another bullish press release about EDSIVO on April 16, 2019 (the "April 16, 2019 Press Release"). The April 16, 2019 Press Release announced the publication of the Long-Term Observational Study, "long-term data from a cohort of COL3A1-positive vEDS patients in the *Journal of the American College of Cardiology*" based on a registry of vEDS patients in France. According to the April 16, 2019 Press Release, the Long-Term Observational Study, entitled "Vascular Ehlers-Danlos Syndrome: Long-Term Observational Study," and authored by Michael Frank, MD, Xavier Jeunemaitre, MD, PhD, and Pierre Boutouyrie, MD, PhD, et al., "describes outcomes in 144 COL3A1-positive vEDS patients clinically monitored and treated at the French National Referral Center for Rare Vascular Diseases (Paris, France) between the years 2000 and 2017." The April 16, 2019 Press Release quotes Dr. Michael Frank, a clinical investigator from the Paris Group and one of the co-authors of the Long-Term Observational Study, as stating, "the higher overall survival in patients treated with celiprolol in this long-term study in COL3A1-positive vEDS patients appears to correlate with the significant event-free survival advantage that was reported in the [Ong Trial] of celiprolol treatment in vEDS patients." The April 16, 2019 Press Release also quoted Acer's chief medical officer as stating: "We are pleased to see this publication from the vEDS clinical investigator group in Paris which provides patients and physicians with a greater understanding of this chronic disease, including data suggesting a positive impact of celiprolol, which has a unique pharmacological profile."

139. On May 14, 2019, Acer issued another press release touting EDSIVO's prospects (the "May 14, 2019 Press Release"), which it attached to a Form 8-K it filed with the SEC. The May 14, 2019 Press Release quoted Defendant Schelling as saying that "[b]uilding on our success in 2018, we continued to execute in the first quarter of 2019 on our pre-commercial launch strategy

for EDSIVO™ (celiprolol) while growing and advancing our product pipeline" and that "[w]ith a targeted FDA PDUFA action date of June 25, 2019, we have made significant progress in preparing for a potential launch of EDSIVO™, including the addition of seasoned commercial and medical affairs leaders with extensive sales, marketing, market access and product launch experience in orphan and ultra-orphan markets" The May 14, 2019 Press Release further quoted Defendant Schelling as saying that "[i]n April 2019, we announced the publication of the Paris registry data in JACC that supplements the previously-reported safety and efficacy of celiprolol in vEDS patients with a confirmed type III collagen (COL3A1) mutation."

140. Notably, in additional to misleadingly portraying the Ong Trial and EDSIVO's chances of approval, the April 16, 2019 and May 14, 2019 Press Releases touted the "positive impact of celiprolol" supposedly observed in the Long-Term Observational Study, while failing to mention the significant limitations of that study. According to the researchers of the Long-Term Observational Study themselves, "[i]t is difficult to formally assess this beneficial effect (the benefit of celiprolol on survival) in the absence of a placebo-controlled prospective trial, because other confounders might have influenced this observation." As Dr. Julie De Backer and Dr. Tine De Backer, vEDS researchers not affiliated with the Long-Term Observational Study, stated:

> Whether the systematic treatment with celiprolol has an additional genuine pharmacological beneficial effect or helps ensure better follow up cannot be answered with this study. The only way to determine if it is celiprolol contributing to the better outcome is to conduct a randomized prospective trial comparing celiprolol to another beta-blocker in patients with molecularly confirmed vEDS.[13]

[13] De Backer, Julie and Tine De Backer, "Vascular Ehlers-Danlos Syndrome Management: The Paris Way, A Step Forward on a Long Road," *Journal of the American College of Cardiology*, Vol. 73, Issue 15 (April 2019).

The FDA Issues a CRL to Acer for EDSIVO, revealing that it had never agreed that additional clinical development was not needed for EDSIVO and that it believed that the Ong Trial was not adequate or well controlled.

141. On June 24, 2019, the FDA issued a CRL rejecting Acer's NDA for EDSIVO. Defendants produced a copy of the CRL from their files to Plaintiff and it is attached as **Exhibit 11**.

142. The CRL could not have been a surprise to Acer since it stated that FDA determined that the Ong Trial did not provide substantial evidence of the effectiveness of celiprolol for the same reasons — concerns about the interim analysis and the premature termination of the Trial and imbalances in the celiprolol and control groups in the Trial — that it had continuously warned Acer about for years:

> We have concluded that the Beta-Blocker in Ehlers-Danlos Syndrome Treatment (BBEST) trial ***does not provide substantial evidence of effectiveness for celiprolol for the reduction of cardiac or arterial events (rupture or dissection) in patients with vascular Ehlers-Danlos Syndrome (vEDS)*** who have a confirmed type III collagen (COL3Al) mutation. Our conclusion is based on the following considerations: ***1) the statistical boundary conditions that were established to adjust for multiple interim analyses (Whitehead's Triangular Monitoring Design) were not satisfied when the study was terminated prematurely when only 50% of the planned subjects had been enrolled; 2) the p-value for the primary endpoint was not adjusted for multiple interim analyses; 3) there were important baseline imbalances*** for which adjustment would increase the p-value to 0.09 (using the stratified log-rank test) and to 0.11 (using the stratified permutation test).

(Exhibit 11 at ACER_0002670 (emphasis added).)

143. The CRL further stated: "To address these issues, ***it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS.***" (*Id.* (emphasis added).) The CRL also noted that "[t]he COL3Al mutation was not confirmed in a substantial fraction of patients enrolled in BBEST. For a future study, we recommend you attempt to confirm the molecular diagnosis in study participants." (*Id.*

at ACER_0002672.)

144. On June 25, 2019, Defendants issued a press release (the "June 25, 2019 Press Release") disclosing that the FDA issued a CRL rejecting Acer's NDA for EDSIVO. Although Defendants did not make the CRL available to the public, the June 25, 2019 Press Release reported that the CRL had cited the need for an "adequate and well-controlled trial" evaluating EDSIVO's effectiveness in reducing the risk of clinical events in patients with vEDS. The June 25, 2019 Press Release also quoted Defendant Schelling as stating the following: "We remain committed to working closely with the FDA to fully understand its response. We expect to respond to the FDA in the third quarter of this year."

145. On July 5, 2019, Defendants issued a press release (the "July 5, 2019 Press Release") announcing that, in light of the FDA's issuance of the CRL to Acer regarding its NDA for EDSIVO, the Company was undergoing a "corporate restructuring," as a result of which "Acer's headcount has been reduced from 48 to 19 employees and pre-commercial activities of EDSIVO (celiprolol) have been halted. The restructuring is expected to provide the resources needed for Acer to conduct its planned business operations through 2020." The July 5, 2019 Press Release also noted that Defendants "intend to continue our dialogue with the FDA to fully understand its response and work toward our goal of approval of EDSIVO." Defendants added that "[i]n light of the CRL it was necessary to reduce our expenses, extend our cash runway, and focus our resources on a potential path forward for EDSIVO as well as continued development of our other pipeline opportunities."

146. The Ehlers-Danlos Society and Marfan Foundation both issued statements supporting the FDA's rejection of EDSIVO's NDA.

147. The Ehlers-Danlos Society's "Consensus statement from the Ehlers-Danlos Society

and professional members of the vEDS community," published on August 9, 2019, stated that "[t]here is not enough evidence to know for sure whether people with vEDS should take celiprolol or another medication to manage blood pressure to try to change the rate of arterial complications" and "that rigorously designed prospective, randomized, double-blinded clinical trials, in individuals with genetically confirmed vEDS are of key importance to guide future therapy in vEDS."

148. The Marfan Fountain's June 25, 2019 "Statement on Celiprolol" discussed the limitations of the Ong Trial and said stated that "[t]he Marfan Foundation, as well as representatives of its Professional Advisory Board, have reviewed the underlying studies of the drug and agree that celiprolol does not warrant designation as a sole approved drug for the treatment of people with vEDS."

149. Plaintiff's investigator spoke with a senior officer at the Marfan Foundation (the "Marfan Senior Officer") who had held the position since 2016 and help draft the "Marfan Foundation Statement on Celiprolol." The Marfan Senior Officer said that the statement was approved unanimously by all 18 members of the foundation's Professional Advisory Board and was driven by cardiologists and geneticists. The Marfan Senior Officer further stated that the Professional Advisory Board did not want to see the drug move forward in the United States because they believed the Ong Trial "was way too small and the results were not significant enough" to support approval. The Marfan Senior Officer also stated that that the Professional Advisory Board did not want to support approval for a very expensive drug when its efficacy was "not even marginal." The Marfan Foundation issued the statement to show vEDS patients that experts on the disease had found the FDA's decision to be sound.

150. Additionally, Defendants could not have been surprised by the Marfan

Foundation's statement. The Marfan Senior Officer told Plaintiff's investigator about having heard that Acer employees had met with the Marfan Foundation's Professional Advisory Board about EDSIVO and that several members of the board told the Acer employees that they did not support approval for the drug.

151. Even in the face of FDA criticism of its EDVISO's NDA, Defendants would have been highly motivated to avoid conducting a new prospective trial for EDSIVO because conducting such a trial would be incredibly expensive and time consuming. In Expert Lavin's opinion, the FDA would prefer a randomized clinical trial with a 1:1 allocation between celiprolol plus standard of care versus the standard of care alone. To detect a 20% absolute advantage in 5-year all-cause survival from 50% to 70% with 80% power for a two-sided log rank test with 5% error, 96 vEDS subjects would be required per treatment group with 71 arterial events[14] required to complete the study. Assuming two years to recruit a total of 200 vEDS subjects, it would take 7 to 8 years to reach the targeted number of arterial events (71). Given that it would be a difficult international study to coordinate, the estimated cost of the trial would be $40,000 per subject or $8,000,000 total (for 200 patients) when the cost of study drugs, study-directed testing, patient follow-up visits, a contract research organization, and site costs are considered. The cost estimate would include a Data Safety Monitoring Committee, a Steering Committee, and a Clinical Endpoint Committee to evaluate disease-specific progression as a surrogate for mortality.

MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED DURING THE CLASS PERIOD

152. The Class Period begins on September 25, 2017, when Defendants issued the September 25, 2017 Press Release touting the "positive results" from Acer's retrospective source verified analysis of the Ong Trial. The September 25, 2017 Press Release further stated that the

[14] Arterial events were the primary endpoint of the Ong Trial.

results of the Ong Trial had achieved "statistical significance" and quoted Defendant Schelling as stating "[w]e continue to successfully rapidly advance our lead product candidate, EDSIVO™,… towards an NDA filing" and that they had "source verif[ied] a definitive Event-Free Survival endpoint from a previously completed robust clinical study."

> ***Acer…today announced positive results from the pivotal clinical trial of EDSIVO™ (celiprolol)*** for the treatment of vascular Ehlers-Danlos Syndrome (vEDS). ***Acer's retrospective source verified analysis of the trial data, including the primary and secondary endpoints, confirmed the data from a previously published randomized controlled clinical study of celiprolol. Acer will use this pivotal clinical data to support a New Drug Application (NDA) regulatory filing in the U.S. in the first half of 2018.…The previously completed European study, published on October 30, 2010, in The Lancet, was stopped early having achieved statistical significance in its primary endpoints***, with arterial dissection or rupture affecting 5 (20%) celiprolol patients and 14 (50%) subjects in the non-treated control group (hazard ratio [HR] 0.36; p-value 0.04). The combined primary and secondary endpoints of intestinal or uterine rupture affected 6 (24%) celiprolol patients and 17 (61%) subjects in the non-treated control group (HR 0.31; p-value 0.01). The study was conducted in 53 patients, who were randomly assigned either a twice daily treatment of celiprolol or no treatment. Mean duration of follow-up was 47 months prior to trial halt. "We are committed to bringing EDSIVO™ to vEDS patients who currently do not have access to this treatment," said Robert D. Steiner, M.D., Chief Medical Officer of Acer. "Our confirmation of the published celiprolol clinical data with an Acer-sponsored retrospective source verified analysis of the trial data represents a critical element of the clinical module in our NDA, which we are diligently building, along with current manufacturing, non-clinical and other components of the regulatory package." **"*We continue to successfully rapidly advance our lead product candidate, EDSIVO™, a potential life-saving therapy for patients with vEDS, towards an NDA filing, which we expect to accomplish in the first half of 2018," said Chris Schelling, CEO and Founder of Acer. "In addition to source verifying a definitive Event-Free Survival endpoint from a previously completed robust clinical study***, modernizing manufacturing and assembling other components of the regulatory package, we are executing on a number of key medical affairs focused initiatives for vEDS patients.

(emphasis added).

153. The bold and italicized portion of the foregoing statements were materially false and misleading because Defendants failed to disclose that 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017 meeting that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

154. On September 26, 2017, Defendant Schelling delivered the September 26, 2017 Presentation at the Cantor Fitzgerald Global Healthcare Conference in New York City. On the same day, Acer filed a Form 8-K with the SEC, signed by Defendant Palmin, that attached the September 26, 2017 Presentation. According to press releases issued by Acer, Defendant Schelling also gave investor presentations on January 10, 2018 at the 2018 Biotech Showcase Conference in San Francisco, California, on February 15, 2018 at the LEERINK Partners 7th Annual Global Healthcare Conference in New York City, and on March 13, 2018 at the 30th Annual ROTH Conference in Laguna Niguel, California.

155. Slide 7 of the September 26, 2017 Presentation stated that "***EDSIVO™ (celiprolol) showed statistically-significant improvement in event-free survival (EFS) compared to control in vEDS patients***." (emphasis added).

156. Slide 11 of the September 26, 2017 presentation stated that in the Ong Trial

"***[i]mportant phenotype characteristics [were] equally balanced between celiprolol and control***." (emphasis added).

157. Slide 12 of the September 26, 2017 Presentation, which discussed the results of the Ong Trial, was entitled "***EDSIVO™ Statistically Significant Efficacy***" (emphasis added).

158. The statements in Paragraphs 155-157 were materially false and misleading because Defendants failed to disclose that 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017 meeting that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

159. On November 14, 2017 Acer filed a Post-Effective Amendment to Form S-3 Registration Statement, signed by Defendants Schelling and Palmin, that included the November 14, 2017 Preliminary Prospectus. The Company filed a Notice of Effectiveness with the SEC on November 21, 2017 making that post-effective amendment to its registration statement effective. After the market closed on December 11, 2017, Acer announced a secondary public offering of common stock.[15] On the same day, Acer filed the final version of the November 14, 2017 Preliminary Prospectus, which was dated November 21, 2017 and the December 11, 2017 Preliminary Prospectus Supplement with the SEC. On December 12, 2017, Acer filed the

[15] Research shows that the share price of a company generally drops when it announces a secondary offering.

December 12, 2017 Prospectus Supplement. In the November 14, 2017 Preliminary Prospectus, November 21, 2017 Prospectus, the December 11, 2017 Preliminary Prospectus Supplement, and December 12, 2017 Prospectus Supplement,[16] Defendants stated:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. At that meeting, the FDA agreed that additional clinical development is not needed and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS.*** In addition, the FDA advised us that no significant additional work would be required for the chemistry, manufacturing and controls, nonclinical or pharmacology sections of the NDA. The FDA also indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO would qualify for priority review, which provides an expedited six-month review cycle, instead of the traditional ten-month cycle, for a drug that treats a serious condition and demonstrates the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is submitted. We expect to submit to the FDA the 505(b)(2) NDA for EDSIVO for the treatment of vEDS in the first half of 2018.

(emphasis added).

160. The foregoing statements were materially false and misleading because Defendants knew or recklessly disregarded that the FDA did not enter into any such agreement with Defendants that no further clinical development would be required for Acer to obtain FDA approval for EDSIVO. Additionally, the Defendants failed to disclose that 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017 meeting that the Ong Trial were flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of

[16] The November 14, 2017 Preliminary Prospectus, November 21, 2017 Prospectus, the December 11, 2017 Preliminary Prospectus Supplement, and December 12, 2017 Prospectus Supplement all formed part of a registration statement signed by Defendants Schelling and Palmin. The language quoted immediately below is identical.

celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. By misrepresenting the FDA's communications to Acer regarding the need for further clinical development to obtain FDA approval, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

161. On March 7, 2018, Acer filed the 2017 10-K with the SEC. Defendants Schelling and Palmin signed the 2017 10-K and the 2017 10-K also contained certifications required pursuant to SOX that Schelling and Palmin signed.

162. The 2017 10-K stated that "important phenotype characteristics" were "equally balanced" between celiprolol and the control groups in the Ong Trial:

> Fifty-three participants were enrolled in the Ong trial and randomized at eight centers in France and one center in Belgium. Patient ages ranged from 15 to 65 (with a mean age of 35), with a female-to-male ratio of 2-to-1. Patients were randomly assigned to a five-year intervention, receiving either celiprolol or no treatment, ***with important phenotype characteristics equally balanced between the celiprolol group and the control group.***

(emphasis added).

163. The foregoing statements were materially false and misleading because Defendants failed to disclose that the FDA warned Defendants at their May 18, 2017 meeting that the Ong Trial was flawed because the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol. By failing to disclose this communication with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

164. The 2017 10-K stated the following concerning Acer's September 30, 2015 meeting with the FDA:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO. At that meeting, the FDA agreed that an additional clinical trial is not likely needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO for the treatment of vEDS. The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing.

(emphasis added).

165. The foregoing statements were materially false and misleading because Defendants knew or recklessly disregarded that the FDA did not enter into any such agreement with Defendants that no additional clinical trial would be required for Acer to obtain FDA approval for EDSIVO. Additionally, the Defendants failed to disclose that 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017 meeting that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. By misrepresenting the FDA's communications to Acer regarding the need for further clinical development to obtain FDA approval, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

166. Defendants also stated the following about Acer's May 2017 Meeting with the FDA in the 2017 10-K:

> In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, ***the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing***.

(emphasis added).

167. The foregoing statements are materially false and misleading because they failed to disclose that 1) the FDA told Acer that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Acer at their May 18, 2017 meeting that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control group biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. These statements were further misleading because the FDA criticisms were not limited to "guidance on the expected presentation of the existing clinical data for EDSIVO™." Instead of being "guidance on the expected presentation of" data, the FDA's criticisms about the Ong Trial's randomization imbalance and termination due to improper interim analyses concerned flaws in how the Ong Trial was originally conducted that could not be remedied after-the-fact. By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

168. On June 29, 2018, Acer filed a Form 8-K with the SEC, signed by Defendant Palmin, that attached the June 29, 2018 Presentation, an updated version of its "Investor

Presentation that will be available on the Investor Relations page of the Company's website at https://acertx.com/investor-relations and will be used at investor and other meetings." According to press releases issued by Acer, Acer's management team made investor presentations on September 5, 2018 at the H.C. Wainwright 20th Annual Global Investment Conference in New York City, on the October 3, 2018 at the 2018 Cantor Fitzgerald Global Healthcare Conference in New York City, and on November 28, 2018 Evercore ISI HealthConX Conference in Boston, Massachusetts.

169. Slide 7 of the June 29, 2018 Presentation stated that "***EDSIVO™ (celiprolol) showed statistically-significant improvement in event-free survival (EFS) compared to control in vEDS patients***." (emphasis added).

170. Slide 10 of the June 29, 2018 Presentation stated that in the Ong Trial "***[i]mportant phenotype characteristics [were] equally balanced between celiprolol and control***." (emphasis added).

171. Slide 11 of the June 29, 2018 Presentation, which discussed the results of the Ong Trial, was entitled "***EDSIVO™ Statistically Significant Efficacy***" (emphasis added).

172. Slide 14 of the June 29, 2018 Presentation stated that the Ong Trial showed "***Statistically-significant improvement in 1⁰ endpoint EFS (p=0.04)***[.]" (emphasis added).

173. The statements in Paragraphs 169-172 were materially false and misleading because Defendants failed to disclose that 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017 and June 14, 2018 meetings that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol,

and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

174. Acer filed the July 31, 2018 Preliminary Prospectus Supplement with the SEC in connection with a secondary public offering of common stock on July 31, 2018, and the August 1, 2018 Prospectus Supplement on August 1, 2018.[17]

175. The July 31, 2018 Preliminary Prospectus Supplement and August 1, 2018 Prospectus Supplement stated that "important phenotype characteristics" were "equally balanced" between celiprolol and the control groups in the Ong Trial:

> Fifty-three participants were enrolled in the Ong trial and randomized at eight centers in France and one center in Belgium. Patient ages ranged from 15 to 65 (with a mean age of 35), with a female-to-male ratio of 2-to-1. Patients were randomly assigned to a five-year intervention, receiving either celiprolol or no treatment, ***with important phenotype characteristics equally balanced between the celiprolol group and the control group.***

(emphasis added).

176. The foregoing statements were materially false and misleading because Defendants failed to disclose that the FDA warned Defendants at their May 18, 2017 and June 14, 2018 meetings that the Ong Trial was flawed because the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol. By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood

[17] The July 31, 2018 Preliminary Prospectus Supplement and August 1, 2018 Prospectus Supplement formed part of a registration statement signed by Defendants Schelling and Palmin. The language quoted immediately below is identical.

of and timeline for FDA approval of EDSIVO.

177. In the July 31, 2018 Preliminary Prospectus Supplement and August 1, 2018 Prospectus Supplement, Defendants stated the following concerning Acer's September 30, 2015 meeting with the FDA:

> ***In September 2015, we met with the FDA to discuss the existing clinical data for EDSIVO™. At that meeting, the FDA agreed that an additional clinical trial is not likely needed*** and stated that we may submit a 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS. The FDA indicated to us at that time that it expected that the 505(b)(2) NDA for EDSIVO™ is likely to qualify for priority review. Priority review provides an expedited six-month review cycle after acceptance of the NDA for filing, instead of the traditional ten-month review cycle, for drugs that treat a serious condition and demonstrate the potential to be a significant improvement in safety or effectiveness of the treatment, prevention, or diagnosis of the condition. The FDA determines whether an application will receive priority review at the time the application is accepted for filing.

(emphasis added).

178. The foregoing statements were materially false and misleading because Defendants knew or recklessly disregarded that the FDA did not enter into any such agreement with Defendants that no additional clinical trial would be required for Acer to obtain FDA approval for EDSIVO. Additionally, the Defendants failed to disclose that 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA and that it "could only decide on the adequacy of the data to support filing, efficacy and safety after our review" in its official responses to Acer's questions for its June 28, 2018 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017 and June 14, 2018 meetings that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for

the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. By misrepresenting the FDA's communications to Acer regarding the need for further clinical development to obtain FDA approval, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

179. In the July 31, 2018 Preliminary Prospectus Supplement and August 1, 2018 Prospectus Supplement, Defendants also stated the following about Acer's May 2017 and June 2018 meetings with the FDA:

> In May 2017, we held a Type C meeting with the FDA to discuss non-clinical and manufacturing data, and proactively identify whether there were any gaps for us to address in advance of a pre-NDA meeting. In our non-clinical data package, we are addressing a potential preclinical gap by conducting in vitro drug-drug interaction studies, which were missing from the Aventis MHRA dossier. We also reached agreement with the FDA regarding Chemistry, Manufacturing and Controls (CMC) specifications. Furthermore, ***the FDA provided us with additional guidance on the expected presentation of the existing clinical data for EDSIVO™ to support the NDA filing.***
>
> In June 2018, we held a Type C meeting and a Type B (pre-NDA) meeting with the FDA. We expect to submit the 505(b)(2) NDA for EDSIVO™ for the treatment of vEDS early in the fourth quarter of 2018.

(emphasis added).

180. The foregoing statements were materially false and misleading because they failed to disclose that 1) the FDA told Acer that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA and that it "could only decide on the adequacy of the data to support filing, efficacy and safety after our review" in its official responses to Acer's questions for its June 28, 2018 meeting with the FDA; and 2) the FDA warned Acer at their May 18, 2017 and June 14, 2018 meetings that the Ong Trial was flawed

because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. These statements were further misleading because the FDA criticisms were not limited to "guidance on the expected presentation of the existing clinical data for EDSIVO™." Instead of being "guidance on the expected presentation of" data, the FDA's criticisms about the Ong Trial's randomization imbalance and termination due to improper interim analyses concerned flaws in how the Ong Trial was originally conducted that could not be remedied after-the-fact. By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

181. On January 7, 2019, Acer filed a Form 8-K with the SEC, signed by Defendant Palmin, that attached the January 7, 2019 Presentation, an updated version of its "Investor Presentation that will be available on the Investor Relations page of the Company's website at https://acertx.com/investor-relations and will be used at investor and other meetings." According to press releases issued by Acer, Acer's management team made investor presentations on January 10, 2019 at the 2019 San Francisco Biotech Showcase in San Francisco California and on March 18, 2019 at the 2019 ROTH Conference in Laguna Niguel, California.

182. Slide 7 of the January 7, 2019 Presentation stated that "***EDSIVO™ (celiprolol) showed statistically-significant improvement in event-free survival (EFS) compared to control in vEDS patients (n=53)***." (emphasis added).

183. Slide 10 of the January 7, 2019 Presentation, which discussed the results of the Ong Trial, stated that they showed "**Statistically Significant Efficacy**." (emphasis in original).

184. The statements in Paragraphs 182-183 were materially false and misleading because Defendants failed to disclose that 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017, June 14, 2018, and February 11, 2019 meetings and in the December 21, 2018 Letter that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. The FDA stated in the February 11, 2019 meeting that the Ong Trial showed "[i]nconclusive efficacy" and that the "[b]aseline imbalances impact[ed] statistical significance." By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

185. On March 7, 2019, Acer filed the 2018 10-K with the SEC. Defendants Schelling and Palmin signed the 2018 10-K and the 2018 10-K also contained certifications required pursuant to SOX that Schelling and Palmin signed.

186. The 2018 10-K stated that "important phenotype characteristics" were "equally balanced" between celiprolol and the control groups in the Ong Trial:

> Fifty-three participants were enrolled in the Ong trial and randomized at eight centers in France and one center in Belgium. Patient ages ranged from 15 to 65 (with a mean age of 35), with a female-to-male ratio of 2-to-1. Patients were randomly assigned to a five-year intervention, receiving either celiprolol or no treatment, ***with important phenotype characteristics equally balanced between the celiprolol group and the control group.***

(emphasis added).

187. The foregoing statements were materially false and misleading because Defendants failed to disclose that the FDA warned Defendants at their May 18, 2017, June 14, 2018, and February 11, 2019 meetings and in the December 21, 2018 Letter that the Ong Trial was flawed because the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol. The FDA stated in the February 11, 2019 meeting that the "phenotypic presentation" was imbalanced and that the "[b]aseline imbalances impact[ed] statistical significance." By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

188. On April 5, 2019, Acer filed a Form 8-K with the SEC, signed by Defendant Palmin, that attached the April 5, 2019 Presentation, an updated version of its "Investor Presentation that will be available on the Investor Relations page of the Company's website at https://acertx.com/investor-relations and will be used at investor and other meetings." According to press releases issued by Acer, Acer's management team made investor presentations on April 10, 2019 at the Needham & Company 18th Annual Healthcare Conference in New York City, on May 21, 2019 at the 2019 UBS Global Healthcare Conference in New York City, on June 5, 2019 at the William Blair 2019 Growth Stock Conference in Chicago, Illinois, on June 6, 2019 at the Jefferies 2019 Healthcare Conference in New York City, and on June 19, 2019 at the Raymond James Life Sciences & MedTech Conference in New York City.

189. Slide 7 of the April 5, 2019 Presentation stated that "***EDSIVO™ (celiprolol) showed statistically-significant improvement in event-free survival (EFS) compared to control in vEDS patients (n=53)***." (emphasis added).

190. Slide 10 of the April 5, 2019 Presentation, which discussed the results of the Ong Trial, stated that they showed "**Statistically Significant Efficacy**." (emphasis in original).

191. The statements in Paragraphs 189-190 were materially false and misleading because Defendants failed to disclose that 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017, June 14, 2018, February 11, 2019, and April 9, 2019 meetings and in the December 21, 2018 Letter and Late Cycle Meeting background package that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. The FDA stated in the February 11, 2019 and April 9, 2019 meetings and in the Late Cycle Meeting background package that the Ong Trial showed "[i]nconclusive efficacy" and that the baseline imbalances "impact[ed] statistical significance" and "render[ed] the treatment effect non-significant" and Acer admitted during the April 9, 2019 meeting that the Ong Trial was stopped prematurely. By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

192. On May 14, 2019, Acer filed a Form 8-K with the SEC signed by Defendant Palmin that attached the May 14, 2019 Press Release. The May 14, 2019 Press Release, quoted Defendant Schelling as stating:

> "Building on our success in 2018, we continued to execute in the first quarter of 2019 on our pre-commercial launch strategy for EDSIVO™ (celiprolol) while growing and advancing our product pipeline," said Chris Schelling, CEO and Founder of Acer. "With a targeted FDA PDUFA action date of June 25, 2019, ***we have made significant progress in preparing for a potential launch of EDSIVO™***, including the addition of seasoned commercial and medical affairs leaders with extensive sales, marketing, market

> access and product launch experience in orphan and ultra-orphan markets**.** Also, in April 2019, we announced the publication of the Paris registry data in JACC that ***supplements the previously-reported safety and efficacy of celiprolol in vEDS patients with a confirmed type III collagen (COL3A1) mutation***."

(emphasis added).

193. The foregoing statements were materially false and misleading because Defendants failed to disclose: 1) the FDA told Defendants that approval based on a single study is rare in its official responses to Acer's questions for its September 30, 2015 meeting with the FDA; and 2) the FDA warned Defendants at their May 18, 2017, June 14, 2018, February 11, 2019, and April 9, 2019 meetings and in the December 21, 2018 Letter and Late Cycle Meeting background package that the Ong Trial was flawed because (i) the randomization imbalance in major diagnostic criteria between the celiprolol and control groups biased the Trial in favor of celiprolol, and (ii) the Ong Trial results were not properly adjusted for the multiple interim analyses conducted and that stopping the Trial early based on those improperly conducted interim analyses rendered the results biased, unreliable, and not statistically significant. The FDA stated in the February 11, 2019 and April 9, 2019 meetings and in the Late Cycle Meeting background package that the Ong Trial showed "[i]nconclusive efficacy" and that the baseline imbalances "impact[ed] statistical significance" and "render[ed] the treatment effect non-significant" and Acer admitted during the April 9, 2019 meeting that the Ong Trial was stopped prematurely. By failing to disclose these communications with the FDA, Defendants misled investors about the likelihood of and timeline for FDA approval of EDSIVO.

LOSS CAUSATION

194. On June 25, 2019, Defendants issued the June 25, 2019 Press Release, which revealed that the FDA had rejected Acer's NDA for EDSIVO. According to the June 25, 2019 Press Release, in the CRL the FDA cited the need for an "adequate and well-controlled trial"

evaluating EDSIVO's effectiveness in reducing the risk of clinical events in patients with vEDS. Specifically, the June 25, 2019 Press Release stated, in pertinent part, the following:

> Acer Therapeutics Inc. (Nasdaq: ACER), a pharmaceutical company focused on the acquisition, development and commercialization of therapies for serious rare and life-threatening diseases with significant unmet medical needs, today announced it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for EDSIVO™ for the treatment of vascular Ehlers-Danlos syndrome (vEDS). The CRL states that it will be necessary to conduct an adequate and well-controlled trial to determine whether celiprolol reduces the risk of clinical events in patients with vEDS. Acer plans to request a meeting to discuss the FDA's response.
>
> "We remain committed to working closely with the FDA to fully understand its response," said Chris Schelling, CEO and Founder of Acer. "We expect to respond to the FDA in the third quarter of this year."

195. On the above news correcting Defendants' prior misrepresentations and omissions of material fact, the per-share price of Acer common stock fell $15.16, or 78.63%, to close at $4.12 per share on June 25, 2019.

196. As a result of Defendants' wrongful acts and omission, and the precipitous decline in the market value of the Company's common stock, Plaintiff and other Class members have suffered significant losses and damages.

ADDITIONAL SCIENTER ALLEGATIONS

Defendants were motivated to make false and misleading statements because Acer needed to raise money to continue as a going concern.

197. By late 2017, Acer had substantial concerns about its ability to continue operations, including its funding of the development of EDSIVO. On November 13, 2017, the Company filed its quarterly report on Form 10-Q for the third quarter of fiscal 2017 (the "3Q2017 10-Q"). In the 3Q2017 10-Q, Defendants stated:

> There is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying financial statements are available to be issued and these financial statements do not include any adjustments relating to the recoverability of recorded asset amounts that might be necessary as a result of the above uncertainty. Based on available resources, the Company believes that its cash and cash equivalents currently on hand are sufficient to fund its anticipated operating and capital requirements through the first half of 2018.

198. Also, in the 3Q2017 10-Q, Defendants stated:

> Our current capital resources are not sufficient to fund our planned operations for the next 12 months. We will continue to require substantial additional capital to continue our clinical development and pursuit of regulatory approval activities. Accordingly, we will need to raise substantial additional capital to continue to fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development, regulatory and commercialization efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop and potentially commercialize (if approved) our product candidates. Based on available resources, we believe that our cash and cash equivalents currently on hand are sufficient to fund our anticipated operating and capital requirements through the first half of 2018.

199. In addition, Defendants stated in the 3Q2017 10-Q the following:

> We expect to incur significant expenses and increasing operating losses for at least the next two years as we initiate and continue the clinical development of, seek regulatory approval for, and potentially commercialize (if approved) our product candidates and add personnel necessary to operate as a public company with an advanced clinical pipeline of product candidates. In addition, operating as a publicly-traded company involves the hiring of additional financial and other personnel, upgrading financial information systems, and incurring costs associated with operating as a public company. We expect that our operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to the timing of clinical development programs, efforts to achieve regulatory approval and planning for potential commercialization (if approved) of our product candidates.

200. The 3Q2017 10-Q further stated "***Our auditors have expressed doubt about our ability to continue as a going concern***" and "[b]ecause we have been issued an opinion by our independent registered public accounting firm that substantial doubt exists as to whether we can continue as a going concern, it may be more difficult for us to attract investors." (emphasis in original).

201. Additionally, the 3Q2017 10-Q stated that "[a]s of September 30, 2017, we had approximately $8.4 million in cash and cash equivalents."

202. On December 11, 2017, Acer issued a press release (the "December 11, 2017 Press Release") announcing the proposed underwritten public offering of common stock. In the December 11, 2017 Press Release, Defendants stated that the Company "intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO™, to invest in pre-commercial activities for EDSIVO™ and for general corporate purposes, including working capital and other general and administrative purposes."

203. In the preliminary and final prospectus and prospectus supplement for that offering, Defendants made the false and misleading statement that "the FDA agreed that additional clinical development is not needed" for EDSIVO.

204. On December 14, 2017, Acer issued a press release (the "December 14, 2017 Press Release") announcing the pricing of its underwritten public offering of common stock. In the December 14, 2017 Press Release, Defendants reported "the closing of the previously announced underwritten public offering of 916,667 shares of its common stock at a price to the public of $12.00 per share." Defendants also stated in the December 14, 2017 Press Release that "[t]he gross proceeds to Acer from this offering were $11.0 million, before deducting the underwriting discount and other estimated offering expenses," and that "Acer intends to use the net proceeds from this

offering to fund its research and development efforts, to seek regulatory approval for EDSIVO™, to invest in pre-commercial activities for EDSIVO and for general corporate purposes, including working capital and other general and administrative purposes."

205. On December 27, 2017, Acer issued a press release (the "December 27, 2017 Press Release") announcing that the underwriters had "partially exercised their over-allotment option by the purchase of an additional 130,000 shares at a price to the public of $12.00 per share, resulting in additional gross proceeds of $1.56 million, before deducting underwriting discounts and commissions and other offering expenses payable by Acer." "After giving effect to the partial exercise of the over-allotment option," according to the December 27, 2017 Press Release, "the total number of shares sold by Acer in the offering increased to 1,046,667 shares and the total gross proceeds increased to $12.56 million." Defendants added: "Acer intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO, to invest in pre-commercial activities for EDSIVO and for general corporate purposes, including working capital and other general and administrative purposes."

206. In the 2017 10-K, Defendants stated:

> On December 14, 2017, the Company closed on an underwritten public offering of its common stock of 916,667 shares at a price of $12.00 per share. The gross proceeds were $11.0 million, before deducting the underwriting discount and other estimated offering expenses. Subsequently, on December 27, 2017, the Company sold an additional 130,000 shares in connection with the over-allotment option granted to the underwriters, for an additional $1.6 million of gross proceeds, before deducting the underwriting discount. The total amount of underwriting discount and other offering costs deducted from gross proceeds was $1.1 million.

207. In addition, the 2017 10-K stated that "[a]s of December 31, 2017, we had approximately $15.6 million in cash and cash equivalents."

208. On May 14, 2018, the Company filed its quarterly report on Form 10-Q for the First quarter of fiscal 2017 (the "3Q2017 10-Q"):

> Based on available resources, the Company believes that its cash and cash equivalents currently on hand are sufficient to fund its anticipated operating and capital requirements through the end of 2018. ***There is substantial doubt about the Company's ability to continue as a going concern within one year after the date that the accompanying financial statements are issued.***

(emphasis added).

209. On May 31, 2018 Acer issued a press release (the "May 31, 2018 Press Release") announcing its intention to offer and sell shares of its common stock in an underwritten public offering. According to the May 31, 2018 Press Release:

> Acer intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO, to invest in pre-commercial activities for EDSIVO, to advance development of ACER-001, to acquire or in-license product candidates, and for general corporate purposes, including working capital and other general and administrative purposes.

210. On August 1, 2018, Acer issued a press release (the "August 1, 2018 Press Release") announcing the pricing of its underwritten public offering. In the August 1, 2018 Press Release, Defendants announced "the pricing of its underwritten public offering of 2,222,222 shares of its common stock at a public offering price of $18.00 per share." "The gross proceeds from the offering, before deducting underwriting discounts and commissions and estimated offering expenses payable by Acer," according to the August 1, 2018 Press Release, "are expected to be approximately $40.0 million." "In addition," Defendants stated, "Acer granted the underwriters in the offering a 30-day option to purchase up to 333,333 additional shares of common stock at the public offering price, less the underwriting discounts and commissions." The August 1, 2018 Press Release further stated:

> Acer intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO, to invest in pre-commercial activities for EDSIVO, to advance development of ACER-001, to acquire or in-license product candidates, and for general corporate purposes, including working capital and other general and administrative purposes.

211. In the preliminary and final prospectus supplement for that offering, Defendants made the false and misleading statements, including that "the FDA agreed that an additional clinical trial is not likely needed" for EDSIVO.

212. On August 3, 2018, the Company issued a press release (the "August 3, 2018 Press Release") announcing the closing of its underwritten public offering. The August 3, 2018 Press Release reported that "[t]he gross proceeds to Acer from this offering are approximately $46.0 million, before deducting underwriting discounts and commissions and estimated offering expenses." The offering consisted of "2,555,555 shares of its common stock, including 333,333 shares sold pursuant to the underwriters' full exercise of their option to purchase additional shares to cover over-allotments, at a public offering price of $18.00 per share." Defendants stated that the Company:

> intends to use the net proceeds from this offering to fund its research and development efforts, to seek regulatory approval for EDSIVO, to invest in pre-commercial activities for EDSIVO, to advance development of ACER-001, to acquire or in-license product candidates, and for general corporate purposes, including working capital and other general and administrative purposes.

213. On March 7, 2019, Acer filed the 2018 10-K. In the 2018 10-K, Defendants stated:

> On August 3, 2018, we completed an underwritten public offering of 2,555,555 shares of common stock at a public offering price of $18.00 per share. We received aggregate net proceeds of approximately $42.7 million, after deducting underwriting discounts, commissions and offering-related expenses of approximately $3.3 million. As of December 31, 2018, we had approximately $41.7 million in cash and cash equivalents.

214. Given that Acer desperately needed cash to continue as a going concern, the Company and Defendants Schelling and Palmin, as President and CEO and CFO, respectively, were highly motivated to misrepresent the FDA's statements about EDSIVO. Furthermore, in light of the Company's precarious situation, any admission that an additional clinical trial for EDSIVO was necessary would have been catastrophic for the Company given the cost and time necessary for the trial as described in Paragraph 151.

Defendants Schelling and Palmin behaved intentionally or recklessly when they approved Acer's SEC filings, press releases, and investor presentations.

215. The FDA's official meeting minutes show that Defendant Schelling attended all of Acer's meetings with the FDA about EDSIVO. Additionally, given the importance of EDSIVO to Acer, it is inconceivable that as President and CEO and CFO, respectively, Defendants Schelling and Palmin would not have been well versed about the FDA's communications with Acer about the drug. Accordingly, they certainly were aware that the FDA had not agreed "that additional clinical development is not needed" or that "an additional clinical trial is not likely needed" for EDSIVO at the time Acer made those statements. Additionally, they were aware of the FDA's criticisms of the Ong Trial and its repeated statements indicating that it was unlikely that it would approve EDSIVO.

216. Each of the Individual Defendants was provided with copies of Company's SEC filings and press releases that contained the misleading statements alleged herein before their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Defendants Schelling and Palmin were, at minimum, reckless when they authorized the issuance of the December 2017 Offering Documents and August 2018 Offering Documents as part of the registration statement they signed. They were also, at minimum, reckless when they signed the 2017 10-K and 2018 10-K and the required SOX certifications that accompanied them. The

SOX certifications for the 2017 10-K and 2018 10-K that Defendants Schelling and Palmin signed stated that "based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." They were also, at minimum, reckless when they signed and/or authorized the issuance of the Form 8-Ks, press releases, and investor presentations quoted above and when they used the investors presentations to give presentations to investors.

217. It is also clear that Defendants intentionally mislead investors based on the revision of their description of FDA's purported agreement with Acer at the September 2015 meeting, as described in Paragraphs 83-88.

There is a strong inference Acer acted with Scienter.

218. Each of the Individual Defendants was a high-ranking management-level employee. The scienter of each of the Individual Defendants and of all other management-level employees of Acer, including each high-ranking officer or director, is imputable to the Company. The knowledge of each of these individuals should therefore be imputed to Acer for the purposes of assessing corporate scienter.

219. Even aside from the scienter of the Individual Defendants, the facts alleged herein raise a strong inference of corporate scienter as to Acer as an entity. Corporate scienter may be alleged independent of individual defendants where a statement is made or approved by a corporate official sufficiently knowledgeable about the company to know the statement was false or misleading. Given the importance of EDSIVO to Acer, the false and misleading statements alleged in this complaint would necessarily have required the approval of a corporate officer with knowledge that they were false and misleading.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

220. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Acer stock during the Class Period and held it until the end of the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants, the officers and directors of Acer, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which the Individual Defendants have or had a controlling interest.

221. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Acer common stock were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class.

222. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

223. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

224. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. whether the federal securities laws were violated by Defendants' acts as alleged herein;

b. whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Acer;

c. whether the Individual Defendants caused Acer to issue false and misleading financial statements during the Class Period;

d. whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

e. whether the prices of Acer common stock during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

f. whether the members of the Class have sustained damages and, if so, what the proper measure of damages is.

225. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

226. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. the Company's common stock are traded in efficient markets;

d. the Company's common stock were liquid and traded with moderate to heavy volume during the Class Period;

e. the Company traded on the NASDAQ, and was covered by multiple analysts;

f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; Plaintiff and members of the Class purchased and/or sold the Company's common stock between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and

g. unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

227. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

228. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

229. Plaintiff repeats and realleges each and every allegation contained above as if fully

set forth herein.

230. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

231. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

232. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

233. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of

the investing public, including Plaintiff and the Class.

234. As a result of the foregoing, the market price of the Company's common stock was artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's common stock during the Class Period in purchasing the Company's common stock at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

235. Had Plaintiff and the other members of the Class been aware that the market price of the Company's common stock had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company and the Individual Defendants did not disclose, they would not have purchased the Company's common stock at the artificially inflated prices that they did, or at all.

236. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

237. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of the Company's common stock during the Class Period.

COUNT II

Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

238. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

239. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

240. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

241. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of the Company within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's common stock.

242. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

243. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: February 4, 2021

THE ROSEN LAW FIRM, P.A.

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Lead Counsel for Lead Plaintiff and the Class

CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2021, I authorized the electronic filing of the foregoing ***Third Amended Class Action Complaint for Violation of the Federal Securities Laws*** with the Clerk of Court using the CM/ECF system, which will send notification of such to all CM/ECF participants.

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